

Development of a Patient Reported Experience Measure in Chronic Obstructive Pulmonary Disease (COPD)

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Abstract

The experience of patients living with chronic obstructive pulmonary disease (COPD) and their views on the quality of healthcare they receive is not currently captured in patient reported measures.

Aim: To develop and validate a patient reported experience measure to assess experiences of living with COPD and perceived quality of healthcare provision.

Method: Previous work with 83 COPD patients identified 38 items for inclusion in a patient reported experience measure. These, together with the COPD Assessment Test and Hospital Anxiety and Depression Scale were administered to patients with COPD. Items demonstrating significant gender or age bias ($p < 0.05$), floor or ceiling effects (set at 40%), missing data $> 15\%$, or high item to item correlations ($r > 0.8$) were removed. Rasch analysis was applied to the remaining items.

Results: 174 patients (Mean age 71 years, SD 9; 91 female; Mean Forced Expiratory Volume₁ 59%, SD 21.9) were studied. 29 items were removed, providing a 9-item unidimensional scale (chi-square $p = 0.33$) with a wide scaling range (logits from -0.1 to +0.2). These cover experiences of living with COPD (e.g. I feel that I am in control of my condition) and health care (e.g. I am concerned that my GP won't listen to my point of view). Internal consistency was good (PSI = 0.77) and correlations between the COPD PREM-9, COPD Assessment Test and Hospital Anxiety and Depression Scale were moderate ($r = 0.42$ and $r = 0.30$, respectively).

Conclusions: The COPD PREM-9 demonstrated good internal reliability and showed a wide scaling range suggesting, regardless of severity, people with COPD can have good or bad experiences. There were low to moderate correlations with the COPD Assessment Test and Hospital Anxiety and Depression Scale, which suggests the PREM COPD-9 is measuring a different concept. The COPD PREM-9 may be a useful measure of quality of care that complements measures of health status and mood.

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Declaration

'Whilst registered as a candidate for this Doctorate, I have not been registered for any other research award. The results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.'

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Abbreviations

BE	Breathe Easy (Groups)
BLF	British Lung Foundation
BTS	British Thoracic Society
CAT	COPD Assessment Test
CCG	Clinical Commissioning Group
CI	Class Intervals
COPD	Chronic Obstructive Pulmonary Disease
CRDQ	Chronic Respiratory Disease Questionnaire
CTT	Classical Test Theory
EU	European Union
EQ5D	European Quality of Life Instrument
FDA	Food and Drug Administration
FEV₁	Forced Expiratory Volume in 1 second
FVC	Forced Vital Capacity
GOLD	Global Obstructive Lung Disease
GP	General Practitioner
GRC	Global Rate of Change Scale
HAD	Hospital Anxiety and Depression Scale
HCPs	Healthcare Professionals
HIEC	Health Innovation Education Cluster
HF	Heart Failure
HQoL	Health related Quality of Life
ILD	Interstitial Lung Disease
ICCs	Interclass correlation coefficients
IRT	Item Response Theory
MRC	Medical Research Council Scale
MS	Multiple Sclerosis
NECLES	North East London, North Central London and Essex
NICE	National Institute of Clinical Excellence

NHS	National Health Service
PR	Pulmonary Rehabilitation
PREM	Patient Reported Experience Measure
PROM	Patient Reported Outcome Measure
PSI	Person Separation Index
QoL	Quality of Life
RCP	Royal College of Physicians
SF36	Short Form (36) Health Survey
SGRQ	St Georges Respiratory Questionnaire
SpO₂	Saturation of Oxygen
SPSS	Statistical Package for the Social Sciences
UK	United Kingdom
WHO	World Health Organisation
6MWT	6 minute walking test
α	Cronbach's Alpha

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Rest in Peace.

Dissemination

2012

Roberts, M., Andrew, S., Walker, S., **Hodson, M.**, & Hudson, R. (2012). Developing a patient reported experience measure for COPD. *European Respiratory Journal*, 40(56), P1464.

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Hodson, M., Andrew, S., & Roberts, C. M. (2013). Towards an understanding of PREMs and PROMs in COPD. *Breathe*, 9(5), 358–364.
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Hodson, M., Yorke., J, Roberts., CM, Andrew., S, Jones, PW. (2014) The development of a Patient Reported Experience Measure in COPD (PREM-COPD Stage 2) *European Respiratory Journal*, 44 (58), P322. (Appendix 10).

CHAPTER ONE

CHAPTER ONE

1. Background context

1.1. Introduction

Chronic Obstructive Pulmonary Disease (COPD) continues to be a significant disease. It is growing globally, estimated to affect between 2–5% of the adult population and is responsible for about 5% of all deaths in England (National Institute of Clinical Excellence [NICE], 2010). It is the second most common cause of emergency admission to hospital. Approximately 14% of patients admitted to hospital with COPD will have died within 90 days, and a further 32% will have been readmitted within the same time span. The 2003 National COPD Audit has shown significant deficiencies in both acute hospital and community care for COPD patients, when measured against guidelines or top quartile performing Trusts (Price et al., 2006). In response to these alarming statistics, the Department of Health has created a National Service Strategy and Framework Document (DoH 2012) which suggests the measurement of patient outcome metrics. These metrics recommend the recording of both Patient Reported Experience Measures (PREMs) and Patient Reported Outcome Measures (PROMs) but currently there are no disease-specific PREMs for COPD (Hodson, Andrew, & Roberts, 2013) that could be used by clinicians to measure the experience of living with COPD. There are, however, a number of PROMs used routinely and extensively within the respiratory community to capture data (Jones et al., 2001). Therefore, this study will seek to develop a validated and reliable new PREM instrument that can be used specifically with patients with COPD to complement the existing PROMs.

This first chapter will introduce COPD as a global disease and its impact on the quality of patients' lives, as well as seek to understand the burden the disease imposes upon patients and the frequent need for people to access healthcare. The reasons for collecting patient data in healthcare will also be discussed defining the national direction. There will be an emphasis on the many different aspects of patient experience, drawing upon the national policies which link together the concept of safety, patient experience and clinical effectiveness which formulates a recipe for quality patient care (Dazi et al., 2008).

This chapter will also discuss the programme of previous work undertaken by the North East London, North Central London and Essex Health Innovation Education Cluster on the initial stages of the development of a new preliminary PREM instrument known as Study One. Chapters Two and Three will explore the current literature behind experience moving to its relationship with COPD and other forms of healthcare measurement. Chapters Four, Five and Six introduce the methodology, the methods and the results of the formation and subsequent development and validation of the new COPD PREM instrument (known from now on as Study Two). The final two chapters, Seven and Eight discuss the findings of the PREM instrument and its proposed and future use within the clinical respiratory field.

1.2. Chronic Obstructive Pulmonary Disease (COPD)

COPD is a complex, long-term condition leading to both high mortality and poor morbidity (Rabe et al., 2007). For people living with the disease it places a heavy burden of symptoms which are often made worse in acute exacerbations or flare-ups of symptoms leading to reduced quality of life. For many people, managing to live with the disease can be isolating and frightening, and can induce high anxiety

and depression (Roche, Chavannes, & Miravittles, 2013) both on the patient and his or her carers.

1.3. Defining Chronic Obstructive Pulmonary Disease (COPD)

COPD is defined as a disease characterised by the presence of airflow obstruction, which is generally progressive, not fully reversible, and not changed markedly over months (NICE 2010). COPD is a universal umbrella term used internationally to describe the irreversible effects of chronic bronchitis, emphysema, and chronic asthma (Calverley, 2013). Although different conditions themselves, there is wide consensus (Global Obstructive Lung Disease [GOLD], 2014), that they are related terms which describe airflow obstruction due to a combination of airway and parenchymal damage. The chronic inflammatory damage in the airways and alveoli results in a loss of elastic recoil, bronchospasm and an increase in sputum production and coughing. Long-standing asthma can also lead to irreversible airflow obstruction (Lange, Parner, Vestbo, Schnohr, & Jensen, 1988, p.1194) and there is, therefore, a clinical overlap between Asthma and COPD (Pauwels & Rabe, 2004, p. 613) in both its chronic and acute forms.

1.3.1. Prevalence

The prevalence of COPD continues to grow due to the growing rate of tobacco use worldwide. However, the disease continues to be mis-diagnosed and its true prevalence is therefore understated. A cross-sectional study of GPs demonstrated that both an observed and modelled COPD prevalence in England ranged from a ratio from 0.20 to 0.95 (Mean 0.52), suggesting, therefore, that this ratio of observed to expected new cases of COPD is low (Nacul et al., 2011). Worldwide, respiratory disease including COPD is the cause of approximately

4.2 million deaths yearly (Wagner & Brath, 2012), and is the fifth leading cause of death in Great Britain (British Lung Foundation [BLF] 2007). Recent research (Shahab et al., 2006) suggests there are 3.7 million people living with COPD in the UK, yet only 900,000 people have been diagnosed with the lung disease (NICE 2004). The World Health Organisation suggests that globally there are 64 million people living with the disease. COPD therefore continues to be a significant burden placed on society across the globe, however exact figures on prevalence of COPD are underestimated and difficult to predict from the literature (Halbert et al., 2003, p.523). In 2010-11 the NHS spent £720 million of its £4 billion respiratory budget (Department of Health [DoH], 2012) on COPD alone with clinical commissioning groups (CCGs) spending an average range of £12m to £40m a year on respiratory disease depending on the CCG's demography and population size.

1.3.2. Clinical Features

COPD is a heterogeneous disease that affects different people in different ways. It is, however, a respiratory disease that can be very disabling due to the symptoms of dyspnoea, fatigue and social isolation caused by embarrassment over chronic sputum production or coughing because of a perceived general lack of understanding over this long-term condition. The disease is predominantly caused by smoking. There are also a number of other factors associated with COPD such as air pollution, socio-economic background, and occupation exposure such as coal miners (NICE 2010). Other respiratory diseases and malnutrition have also been linked to the onset of COPD (World Health Organisation [WHO], 2002).

COPD is diagnosed by clinical judgement including a clinical history of cough, exertional breathlessness, wheeze, winter bronchitis and exposure to risk factors in patients over 35 years (NICE 2004). Objective measurements to confirm the diagnosis of airflow obstruction can be recorded using a spirometer. Airflow obstruction is defined as a reduced Forced Expiratory Volume (FEV₁) in one second and a reduced FEV₁/FVC ratio (Forced Vital Capacity) of less than 70% (NICE 2010). There are now widely accepted pharmacological approaches to optimise the management of COPD in both its acute and chronic setting with the use of inhaled and oral medication (GOLD 2014) along with smoking cessation interventions. More non-pharmacological approaches to COPD care are also recognised, for instance intervention such as Pulmonary Rehabilitation (PR) and breathing control groups.

1.4. National Context of Patient Experience

The national drive to improve the quality of care for patients by putting people at the heart of their own care is not just about being involved in the decisions around care, but also being involved in the experience of healthcare. Being able to record and report the experience alongside the experience of living with the illness or disease is a key factor. But how does the National Health Service (NHS) capture this and what does the bigger picture look like? These are questions that healthcare professionals including nurses need to explore further to generate a greater understanding of why the measurement of patient experience is key to improving and driving quality change in the NHS.

The much-needed national refocus on ensuring that patients remain at the heart of healthcare and reporting patient experience is now becoming an integrated part of

nursing and trust strategies. An historic example of poor experience and care is the high profile case of care at Mid-Staffordshire Hospital. The Francis Report (Francis, 2013, p.41) clearly identified a vast number of systemic failings which led to serious patient harm and where quality and patient experience were not measured or, if they were, the findings were not acted upon. The report also highlighted that patients were not listened to either in a proactive way through feedback or through reactive means such as complaints. This widely publicised report was highly influential, and has led to some of the recent widespread changes in key areas such as Trust values being built upon the expectation of providing quality services. Much of this has been driven by the national focus on and subsequent shift towards listening to the patient voice as a key driver for change, moving away from the traditional NHS focus on activity, waiting times and targets (Raleigh & Foot, 2010). A key recommendation from the Francis report (2013) was recommendation 254: 'the gathering of patient comments and the use of patient feedback.'

In April 2013, changes in the National Health Service and Department of Health refocused on the 'new NHS' with the creation of NHS England and many other authoritative bodies responsible for the patient voice such as Healthwatch and clinical commissioning groups. Within the many new changes in the NHS structure and formation of health policy a domain lead for patient experience along with a further four domains within the newly created NHS England were created. The vision of the new NHS (2013) is that:

Everyone has greater control of their health and their wellbeing, supported to live longer, healthier lives by high quality health and care services that are compassionate, inclusive and constantly improving

The main focus for healthcare providers in delivering this vision is that of a 'high quality' service, and built into this is the need for a 'positive patient experience'. The biggest concept at present by NHS England (2013) is the introduction of the Family and Friends Test by simply asking patients whether they would recommend the hospital, ward or accident and emergency department to a friend or relative and through a transparent NHS this data is published and shared in the public domain. But this doesn't go far enough. Firstly there is little published data on the outputs from the family and friends test. In a study of 142 hospitals, results showed only mild to moderate correlation with other quality indicators such as the NHS inpatient survey (0.46 $p < 0.001$) & hospital mortality indicators (0.21 $p = 0.01$). (Greaves, Lavery, & Millett, 2013, p.396). And if we look further at disease-specific areas, asking such a question has caused distress and anxiety, as demonstrated by a recent letter to the editor of the *BMJ* which suggested such among inpatients living with cancer and receiving chemotherapy (King, Eyre, & Bruce, 2013, p.346). In 2009, a systematic review by Naidu, (2009, p.366) of patient satisfaction made suggestions that friends and family are the observer groups that potentially represent future patients who therefore could become major influencers of patient healthcare choices. The NHS therefore must ensure that patient experience is captured, while not confusing the terminology (between satisfaction and experience).

As well as the previous reports, The NHS Constitution (2013) also makes it clear that 'high quality care is for all' and is key to the success of quality in the NHS by building on the previous work undertaken by Professor Lord Darzi (DoH 2008). He recognised the enduring principles and values of the NHS; the constitution

gives readers clear signposting to the rights and responsibilities for patients, public and staff. Key aspects of this important legislation are:

- Empowering all patients and the public;
- Creating shared purpose, values and principles;
- Strengthening accountability through national standards for patients.

In a subsequent follow-up report in 2009, (*High Quality Care for All – Our Journey So Far*), three defining components which mattered to patients were identified: the effectiveness of care interventions, the experience of the patient and the safe delivery of healthcare (Figure 1.1).

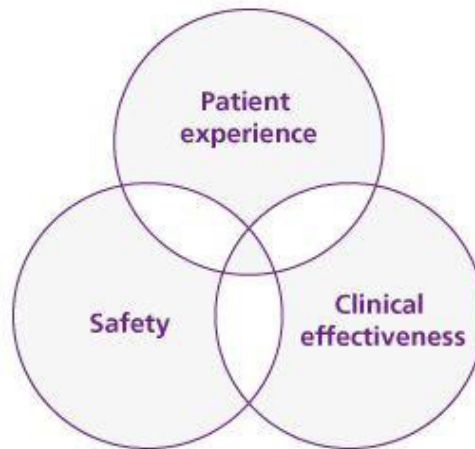


Figure 1.1 Key components to healthcare, according to patient experience

It is these three guiding principles around which quality of care and nursing strategy is now built in many healthcare providers. In 2011, the Department of Health produced the NHS Patient Experience Framework which clearly defines the concepts of healthcare critical to the patient experience, as defined by patients, and will be discussed further within Chapter Two.

The National Institute of Clinical Excellence also worked on the need to develop quality in healthcare and continues to develop the introduction of NICE Quality

Standards which cover diseases and complex health areas from stroke to cancer care. This is aimed at achieving a range of national standards with a central focus on improving quality care in a specific field. To help achieve this, NICE published, in 2012, a quality standard for the patient experience. These are a set of fourteen priorities aimed at improving quality, which would be benchmarked against quality indicators (NICE 2012). These support previous work ensuring that patients are central to care and ensuring the best possible experience of care provided by the NHS. Other countries are also developing government policy in response to growing need. In Australia, for example, the federal policy for long-term conditions is based upon patient experience, and as discussed in the paper by Corcoran et al., (2013, p.19), who emphasise that understanding the patient experience can help influence healthcare providers deliver services based and tailored upon individual patient needs.

The USA, for many years, worked to develop 'patient-centeredness' and improve the patient experience throughout the US Health system. The Picker Institute led the way in programmes of work to capture this through survey design, questionnaires and dissemination of work across the US and the US Department of Health by developing the Human Services National Quality Agenda (Picker Institute, 2013a).

The national UK mandate and focus on experience is complex. There has been a real clear shift within the National Health Service and NHS England to ensure that services, staff and patients play an integral role in the future of the NHS and that patient experience is central to the measurement of quality alongside patient safety and clinical effectiveness.

1.5. Quality Measurement in Healthcare

An appreciation of why we measure in healthcare is an important aspect of ensuring that quality care is being commissioned and delivered. The evaluation of healthcare is continuously evolving with the patient perspective increasingly sought to provide high-quality care for patients at the centre of their own healthcare. The concept of collecting patient data in healthcare will now be explored drawing upon the national direction, and making the association further between quality and patient experience.

'Self-report' questionnaires are increasingly being used to gather information about patients' health-related quality of life. The actual outcomes of the treatment, along with their experience, and the recorded perceptions of care delivered by their own healthcare team are all considered. Patient satisfaction measures may be familiar to clinicians and researchers as they are used routinely in many clinical settings as a benchmark of quality (Crocker, Lewandrowski, Lewandrowski, Gregory, & Lewandrowski, 2013; Wiebe et al., 2014). Patient satisfaction measures, however, have a ceiling effect, a point at which scores for the measurement have reached their highest point, potentially masking the negative health care experience (Hodson et al., 2013, p.359). In many cases, patient satisfaction questionnaires are generic and loosely constructed thereby not supporting any change or adding to the richness of patient experience or disease specific measurement.

1.6. Patient Reported Experience Measures (PREMs) in Context

The main objective of this study is to understand the complex experience of people living with COPD, and the disease's effect on their daily life, as well as their experience of interacting with the healthcare system, for example the

interaction between patients and their General practitioner or COPD team. How this is measured and the descriptors in which patients describe this experience will be a focus of this study.

The strategic development of an overarching programme of work in COPD was begun by the North East London, North Central London and Essex Health Education and Innovation Cluster (NECLES HEIC), in partnership with Anglia Ruskin University of which the author was a fellow. One strand of this work was to measure the patient experience in COPD. The first programme of this work ('Study One') was to develop a set of descriptors and eventually items (a set of questions) to formulate a preliminary instrument to describe the experience of living with COPD and patients' experience of interaction with healthcare professionals. In summary, Study One was a qualitative study resulting in the generation of 52 items using a number of descriptive terms to describe COPD experience, of which further detail is provided in Chapter Two. This work fed into Study Two (this thesis) in which the author led on all aspects of its development with the aim of creating a disease-specific PREM instrument to be used by healthcare professionals aimed at benchmarking and improving the overall quality of care and services for patients living with COPD.

An understanding of different dimensions in COPD care through experience developed from the language and descriptors used by patients to validate and test this PREMs questionnaire in COPD. This questionnaire may help to generate a greater understanding of the patients perspective in providing quality services for people living with COPD in the future, through its potential use in clinical audit or patient assessment. A definition for patient experience is varied (Cornwell, 2012, p.1; Pemberton & Richards, 2013, p.19) and widespread according to its

meaning and measurement in the context of healthcare (Hodson et al., 2013). Currently, measurement of the experience in COPD is by generic instruments and a more disease-specific instrument is needed rather than focussing current assessment around the objective measurements recorded through PROMs, for example walking distance or health-related quality of life. Other PROMs also tend to focus more on areas such as the patient's breathlessness, physical activity and patient reported symptoms such as cough and sputum. PREMs, however, are not only measures, but also provide a more patient-centric view of overall healthcare, but are often confused and used together with no clear definition or are simply measures of patient satisfaction or a form of a PROM.

This study will also make further distinctions between patient satisfaction, PROMs and PREMs as measures of healthcare detailed in Chapter Three. An appreciation of the relevant literature is presented with a clear focus on the need for a definition of experience in healthcare and its relation to the experiences of people living with COPD. The primary objective of this thesis was to develop a new instrument for use to measure the experiences of people living with and their utilisation of healthcare, specifically with those living with COPD.

1.7. Following Chapters

The concept of measuring and generating new ways of recording patients' experience is not a new phenomenon in healthcare, and the Literature Review (Chapter Two) explores this concept, drawing upon the evidence and premise undertaken in Study One that there is currently no published PREMs in COPD and will be discussed further alongside a demonstration of how other instruments for

long term conditions have captured and recorded the patient experience and other measures of quality of life and recording outcome measures (Chapter Three).

Chapters Four to Six convey the original research work conducted in Study Two, with the research plan presented in Chapter Five. The method of reducing items to formulate the final PREM COPD-9 (Figure 7.1), which is a reliable and validated measurement of experience through the application of hierarchical methods of item reduction and Rasch analysis, is discussed further in Chapter Five. Chapter Six explores the preliminary results of reliability testing and the primary structure of the newly created instrument. Chapter Seven discusses testing the instrument with other widely validated instruments in COPD to measure health related quality of life, in discussion with current literature and reported experiences of living with COPD. Finally, Chapter Eight will provide a summary of the study and the implications for clinical practice, personal reflection and suggestion for further research.

It is clear that the focus and shift of the measurement of quality healthcare has moved at a rapid pace and therefore the need to measure the experience of people living with COPD is paramount given the global prevalence the disease imposes on society and the heavy burden of symptoms placed on individuals living with the disease. Developing this instrument can help to evaluate effectively the services that are commissioned using the most appropriate disease-specific tools. Therefore, the COPD-PREM 9 may be a useful measure in clinical audits of quality of care, as well as being useful for patient assessment, and may complement other measures used in COPD care such as health related quality of life questionnaires (Roberts, Andrew, Walker, Hodson, & Hudson, 2012)

CHAPTER TWO

CHAPTER TWO

2. Literature Review

2.1. Introduction

In the opening chapter, COPD was introduced as a long-term condition with a heavy burden of symptoms on the patient's quality of life and healthcare. The national context of NHS healthcare and the need to measure patient experience was also introduced and discussed along with the further need to explore the development of a disease-specific instrument to measure COPD patient experience, known as a PREM.

In Chapter Two we start to examine existing literature around patient experience, discovering what the most important aspects about living with COPD we need to understand, mainly through qualitative methods of data collection and analysis. There are a number of key issues and themes which are important to explore further in the rigorous literature review on experience and COPD. Firstly, however, it is important to understand further the concept of experience and what we mean by it, how we define it, and then drawing the link between quality care and patient safety.

2.2. Experience

There can now only be a general consensus that patient experience is fundamental to the delivery of high quality patient centred care in the NHS and is central to the evaluation of healthcare services and the delivery of quality care, as there is now good evidence (Doyle, Lennox, & Bell, 2013, p.1) that there is

an important and positive relationship between patient experience, effectiveness and safety as outlined in the introduction to this thesis. Black et al., (2014, p.534) found that there was a weak correlation between experience and outcome after knee surgery and therefore, it could be argued that the measurement of clinical outcomes and the views and experiences of patients must be seen as discrete concepts (Graham & MacCormick, 2012).

It is therefore important that the assessment of quality services should potentially include measures of both clinical performance and the experience of patients where possible, the measurement of which will be discussed in more detail in Chapter Three. The definition of experience and the understanding of the basic principles of what we as clinicians mean by experience has become confused in the last twenty years (Hodson et al., 2013, p.359). A simple definition of experience comes from the Oxford English Dictionary (2013, p.214) is an event from which 'you learn, or gain knowledge and skill through practical involvement'

Experience, however, can be broadly categorised in two main areas: firstly, experience which consists of knowledge or skills learnt, for example in a job, or activity such as learning a musical instrument; secondly (and this is closer to the dictionary's definition) experience which is gained through exposure to an event that leads you to make a judgment about part of your life. Therefore, the experience of quality healthcare should be a positive experience and it is critical to ensure that the NHS provides quality, compassionate care, as many people will experience different journeys and come in to contact with healthcare professionals and services, all adding to the creation of 'new knowledge' which leaves an impression long afterwards. The Beryl Institute, an American global

leader of patient experience, cited in LaVela & Gallan (2014, p.29), defines the patient experience as:

the sum of all interactions, shaped by an organization's culture, that influence patient perceptions across the continuum of care.

They also suggest that this is a wide definition, but despite this uncertainty of what to measure or which underlying construct to focus on, there is general consensus that patient experience in a health care framework incorporates the patient's journey as a whole and that it is a significant aspect to measure: clinically, practically and managerially (LaVela & Gallan, 2014).

2.3. Customer experience – has business shaped measurement in health?

There have been a number of publications (Health Foundation [HF] 2013) discussing the different concepts of experience, not just in healthcare, but in many areas of life. The need for consumer feedback is important and has been measured in many different ways such as star ratings, online questionnaires and 'smiley face' rating your experience of service. But exploring further the concept of 'customer experience'. Harvard Business School's suggestion is that customer experience is the internal and subjective response customers have to a direct or indirect contact with a specific company (Meyer & Schwager, 2007, p.2). Direct contact is your experience of interaction with a customer assistant while discussing a product or in the purchasing of goods for example; indirect contact is interaction you have remotely, maybe with a website or an unplanned encounter for example a review of a company in a magazine which talks about others' experiences. But, ultimately, the direct and indirect relationships in consumer markets make a direct impact on the positive or negative experience of an encounter. It is also clear that in customer experience people have

expectations around the service being delivered and these experiences can be instinctively compared either positively or negatively, but it is imperative that these judgments are managed and effectively thought through. It is clear, however, that interest in customer experience has developed over the last five years, as Verhoef et al. (2009, p.31) would argue that in 2009 the current literature, much like the health service, did not see the 'customer experience' as a separate construct or priority and had focussed much more on the satisfaction and service quality in the marketing, retail or service organisation.

For a long time, the US market, for example, have been working hard to develop their customer satisfaction strategy, focusing on two main aspects: high customer satisfaction for service quality; and financial stability, ensuring that companies retain customers (Hayes, 1998). Thus the application of the principles underpinning satisfaction within healthcare were borrowed from the service industry, backed by a tenet of consumerism, and an increasing recognition of service user opinion (Darzi, 2008; Oliver, 1993; Sitzia & Wood, 1997). This concept of improved satisfaction in local services and the growing previous need to evidence positive feedback is even more apparent with healthcare regulators such as the Care Quality Commission (CQC). A growing body of evidence (Fornell, 1992; Narver & Slater, 1990) outside public services suggests that the long-term success of an organisation is undoubtedly based on its capability to react quickly to changing customer needs, preferences and the ability to support a higher competitive position (Bayraktar, Tatoglu, Turkyilmaz, Delen, & Zaim, 2012 pp.99-104).

Taking these concepts further, in the NHS there has been a large number of patient satisfaction scales (Jennings, 2013; Wiebe et al., 2014) developed and

used in practice today which include measurement in specific diseases. Satisfaction tools may be generic, measuring satisfaction with care given by a healthcare professional or service (for example by asking 'would you recommend this GP to others?') or condition specific ('Did your respiratory doctor give you sufficient information about how to manage your COPD?'). A systematic review of factors affecting patient satisfaction and quality by Naidu, (2009, p.367) claims that patient satisfaction is multi-dimensional, affected by a number of variables which affect healthcare quality:

Healthcare quality affects patient satisfaction, which in turn influences positive patient behaviours such as loyalty. Patient satisfaction and healthcare service quality, though difficult to measure, can be operationalised using a multi-disciplinary approach that combines patient inputs as well as expert judgement (Naidu, 2009, p.366).

Ware et al., (1977, p.2-5), through a review of 111 articles on patient satisfaction and healthcare published between 1951 and 1976, identified the main themes as: the technical quality of care, accessibility/convenience; finances (an American study), physical environment, availability, continuity, and outcomes of care. Subsequent summaries (Tucker & Adams, 2001, pp.272-273) of the measurement of satisfaction in healthcare continue to relate to a number of key areas such as the patient's satisfaction in interactions with providers, the ease of access, the burden of costs, and the environmental issues such as cleanliness of the health care facilities. These, of course, remain the foundation of current patient satisfaction with healthcare, and continue to be measured and developed in current healthcare design and structures. For example Weston et al., (2010, p.584) concluded from their systematic literature review that there were no published patient satisfaction questionnaires in sexual health, so used a

qualitative design method to develop and validate an instrument. The results generated by the questionnaire continue to reflect the traditional approach to patient satisfaction, focusing on themes identified back in 1951 such as whether the nurse was 'friendly' and 'approachable' with a scale of 'yes', 'to some extent' and 'no'.

Patient satisfaction scales, however, have a ceiling effect, in that most patients score their care highly, and therefore there may be very little discrimination between items (Andrew, Salamonson, Everett, Halcomb, & Davidson, 2011; Cappelleri, Gerber, Kourides, & Gelfand, 2000) and give very biased results. In clinical circles they are irreverently referred to as the 'happy scale' as illustrated in Figure 2.1 and can only reflect satisfaction in comparison to scales such as the visual pain assessments commonly used in healthcare.

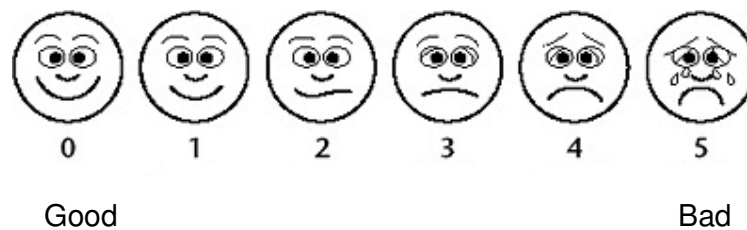


Figure 2.1 Happy scale – example

Clearly, however, not all patients are 'happy' with their care and satisfaction scales may mask negative experiences (Andrew et al., 2011; Williams, Coyle, & Healy, 1998). A study of 21 EU countries (Bleich et al., 2009, p.271) stresses that satisfaction is also linked to much 'broader societal factors' such as the wealth and prosperity of a country. Frustration with patient satisfaction surveys (Bleich et al., 2009; Cleary, Edgman-Levitan, McMullen, & Delbanco, 1992; Cleary, 2009) led to recommendations that the focus should shift from satisfaction with care to patient experience of care. Williams et al., (1998, p.1358) recommended that

High satisfaction ratings do not necessarily mean that patients have had good experiences in relation to that service. If the underlying policy purpose of satisfaction surveys is to provide patients with a voice in the assessment and continuing development of services then it is not adequate to utilise satisfaction survey results. Effort must be put into designing methods of assessing patients' experiences of services and the meaning and value they attach to them, whether these are positive or negative and whether they can be improved.

This is where healthcare professionals' understanding of patient satisfaction and experience is confused by the inconsistent use of terminology. Delnoij (2009, p.354) claims that one of the major problems with patient satisfaction is its indistinctness, being ill defined or not clear in its measurable outcome. And therefore other methods of reporting and collecting data such as the use of PROMs and the further development of PREMs are currently considered alternative ways of collecting, reporting and recording a richer and more relevant set of information than patient satisfaction surveys (Whelan, Reddy, & Andrews, 2011).

Drawing upon previous papers, Tynan & McKechnie (2009, p. 501) claimed the idea of 'customer experience', as holistic – building on the experience of consumers as 'individuals' and as a single voice. This relates well to the holistic needs of individual patients and the concept of patient-centred care, moving away from the traditional patient satisfaction approach. Gentile et al., (2007, p.397) describe the consumer experience as an:

Experience which is strictly personal and implies the customer's involvement at different levels (rational, emotional, sensorial, physical, and spiritual)

Therefore, reflecting back on the overview of constructs of the consumer experience and building up the need for the customers' view point of generating

a customer friendly image, the need for promoting the right patient-centred healthcare is fundamental to all those who are delivering healthcare services such as nurses and allied health professionals. This has been strengthened by the commitment made by the Department of Health and NHS England to embrace and strengthen the need for the 'customers' involvement', if we reflect on the definition by Gentile et al (2007).

Creating and promoting new ways to capture and collate patient experience has evolved over the last ten years (NHS 2013). This evolution has stemmed from the plethora of national policies (NHS Constitution; NICE 2012) and drivers aimed at focusing health service organisations to embed patient experience into organisational strategy, promoting a continued positive patient experience for now and the future. Specifically, the Operating Framework for the NHS 2012/13 states clearly that patient experience should be collected in real time and used to improve local services; whereas, the NHS Outcome Framework, designed to be the overarching strategy for the NHS England, has patient experience as one of five domains aimed at set high-level outcomes to be disseminated throughout the NHS (NHS 2013).

2.4. Patient Experience Overview

We have so far discussed how patient satisfaction and how the business principles of customer satisfaction are linked and the importance of where experience in business has started to influence the direction of quality in this area and therefore underpinning the development of policies and drivers within the NHS as a theme. One milestone in the development of the understanding of patient experience in general was achieved in 2010, in a literature review commissioned

as part of a wider project by the Department of Health and King's Fund called 'What Matters To Patients? Developing the Evidence Base for Measuring and Improving Patient Experience' (Department of Health and Kings Fund, 2010). This report states a number of important aspects to the understanding of patient experience: the clearest is that the number of studies that had been undertaken in patient experience – whether it be a systematic review or results from the NHS national patient NHS survey (Coulter, 2005, p.1119), or more discrete (Cunnett, 2010) trust-wide reports. These findings draw together a common number of similarities in views or opinions by patients in connection with their experience or 'satisfaction' of NHS care. These similarities are evident in 'reports' or research whether their data collection was from a focus group or through postal surveys.

The 'What Matter to Patients' (Kings Fund,2010) report and subsequent work by Coulter et al. (2014 p.119) and Cunnett (2010) now conclude that we have rich data to understand what is important to patients and its relationship is key to the connection that patients expressed in their aspects of care like dignity, empathy and emotional support which are incredibly important in terms of reflecting on the overall patient experience' together with more functional features such as access, waiting, food and noise (Glenn & Cornwell, 2010, p.20). These features of experience are also not dissimilar to the findings of the COPD PREMs Study One work which is picked up later in the second section of this literature review (p.124). The initial definition of experience simply suggested that experience was based upon an impression that the event leaves on 'someone', of course in this context, the 'patient'. The NHS institute for Innovation and Quality have stated that there are a number of different aspects and policy drivers of experience captured

by the health service and that a focussed report from the King's Fund led to the development of a National Patient Experience Framework (Appendix Two).

2.4.1. NHS Patient Experience Framework

So it is clear that these policies (NHS Operating Framework, The NHS Outcomes Framework & NHS Constitution) has focused a more detailed approach to experience and in 2011, the NHS made a commitment to putting patient experience at the centre of its evaluation of the quality of care by developing the NHS Patient Experience Framework (Figure 2.2). The Department of Health made the commitment to develop this framework which was agreed by the NHS Quality Board (NQB) which is a multi-stakeholder board within NHS England to champion quality and ensure alignment in quality throughout the NHS. The aim of the NQB is to bring together all those with an interest in improving quality and embedding this in everything within the NHS, of which patient experience is a driver. The framework is designed to help guide the measurement of patient experience and clarify the critical elements as the guiding principles within the NHS. This framework was based upon the previously discussed research published by the King's Fund and King's College London. A final aspect of this research proposed that it is possible to apply a unified generic framework for patient experience to a large number of health-related conditions and settings, and thus finally recommended that the Department of Health adopted a common single framework for this purpose (DH 2012). The framework however, was modified and is based upon a version of the Picker Institute Principles of Patient-Centred Care, an evidence-based definition of a good patient experience (Picker Institute, 2013b). However, the founding principles remain the same by asking and collecting patient data and utilising these values. The Department of Health (2011) NHS Patient

Experience Framework has eight core concepts to it as outlined in Figure 2.2 which cover a range of different aspects of patient experience.

Figure 2.2 The NHS Patient Experience Framework (DoH 2011)

<p>Respect for patient-centred values, preferences, and expressed needs, including: cultural issues; the dignity, privacy and independence of patients and service users; an awareness of quality-of-life issues; and shared decision making;</p> <p>Coordination and integration of care across the health and social care system;</p> <p>Information, communication, and education on clinical status, progress, prognosis, and processes of care in order to facilitate autonomy, self-care and health promotion;</p> <p>Physical comfort including pain management, help with activities of daily living, and clean and comfortable surroundings;</p> <p>Emotional support and alleviation of fear and anxiety about such issues as clinical status, prognosis, and the impact of illness on patients, their families and their finances;</p> <p>Welcoming the involvement of family and friends, on whom patients and service users rely, in decision-making and demonstrating awareness and accommodation of their needs as care-givers;</p> <p>Transition and continuity as regards information that will help patients care for themselves away from a clinical setting, and coordination, planning, and support to ease transitions;</p> <p>Access to care with attention for example, to time spent waiting for admission or time between admission and placement in a room in an in-patient setting, and waiting time for an appointment or visit in the out-patient, primary care or social care setting.</p>

This framework enables the NHS to meet public expectations by providing concepts which are critical to meet effectively, in a timely manner by clinicians who are skilled and knowledgeable about healthcare. Healthcare should, then, be delivered by workforces who are professional with customer services skills

to match. Acknowledging that quality and patient-centred care must work together to provide effective healthcare services is vital to ensure appropriate measurement with new ideas and instruments. As has previously been mentioned, patient satisfaction has for too long been measured by weak methodologies (Coulter, 2002). Often, many patient satisfaction surveys have focussed on operational aspects of hospital care and failed to explore patient-centred aspects – as highlighted in the patient experience framework (Holmes-Rovner, 2001) – such as communication and co-ordination of care which was evident in the English National Adult Inpatient Survey data. But DeCourcy et al. (2012, p.71), who undertook a systematic search of the English inpatient surveys and grey literature (published work such as specific reports) from 2002 to 2009, conclude that the results of these surveys alone are not adequate to create change to patient experience.

The need for change in the management and assessment of patient experience has, for many decades, been central to health policies and healthcare developments. However, even though it is evident that the patients' experience can bring about improvements in NHS healthcare, the pace of change seems slower than expected with additional pressures on the NHS system such as finance concerns. Budgetary pressures, staffing and an increase in patient demand has compromised quality of care as reported by patients' experience over time (Coulter, 2002, p. 1200). The measurement of experience however, needs to focus more on the individual care and living with diseases rather than the more overarching response to healthcare.

The definition of patient experience is translated across the eight different concepts within the NHS patient experience framework. This allows for a broader,

more personalised view of patient experience, ensuring that, patient centred care is fundamental to the experience and future design of NHS services. Previous work undertaken by Hughes, Bamford, & May, (2008); and Mead & Bower, (2000) on patient-centred care has yielded similar constructs to that of the NHS patient experience framework. A recent study by Luxford et al., (2011, pp.510-515) who used semi-structured interviews with senior clinicians and directors to investigate the facilitators and barriers to patient-centred care in the US, renowned for improving the patient care experience, explained that the 'delivery' of healthcare was a shift towards a 'patient-centred healthcare system' to that of current 'provider-focus' system, but argued that the length of time it took to transition towards such a patient focussed approach relied on key deliverables such as a lack of commitment and clinical leadership, communication and organisational culture. These were perceived as barriers towards providing a more patient centred healthcare focussing on the needs of patients experience and not that of the organisation. Although this is a US study, these are not dissimilar findings to a postal survey of nurses in 20 London hospitals undertaken by West et al., (2005, p.435) who explored the barriers to delivering high quality patient-centred care. West et al. showed time, tools and training were identified as common barriers to providing patient centred care which, of course, leads to poorer patient experience of healthcare. It is clear that experience is captured globally in every setting from retail and marketing to those recorded by health services and the principles discussed regarding how experience is reported and evidenced using different approaches help to understand how experience is seen within healthcare. There are many similarities that can be learnt and shared between business and healthcare. This section gave an overview for the national picture of why the NHS

has become more enriched in patient experience and how experience can drive change if used appropriately and inspired by the NHS patient Experience Framework.

The next step in the development of any new instrument is to explore the existing literature in relation to the disease in question and to gain a greater understanding of its effects on the patient experience. For this study, it was important to identify papers which present the results relating to the measurement of Patient Reported Experience Measures (PREMs) in COPD either as a measure of experience of living with COPD or through utilisation of healthcare services and the appropriate papers to explore the concept of patient experience in COPD.

2.5. COPD Literature review

This next section will include a rigorous literature review to ensure a wide range of literature was searched for existing disease-specific literature relating to COPD and experience. This included English language literature reviews, primary qualitative and quantitative papers and grey literature of high relevance, as well as items with certain keywords in the title or abstract such as 'experience' and 'measure' (Table 2.1). Undertaking a rigorous literature review was fundamental to providing a comprehensive understanding of the experience of people living with COPD and the availability of current patient reported experience instruments in COPD.

2.5.1. Aim

The main aim of this literature review was to explore the current understanding, landscape and practical concepts in PREMs for patients with COPD. The review initially looked at scoping search for both qualitative and quantitative literature that has explored, published or made reference to the development of a COPD PREM instrument or of measurement of experience used in clinical practice. The main search focuses on a rigorous review of the literature that describes the experience of living with COPD, or of healthcare.

The following objectives drove these two approaches:

- A. Is there a disease specific measure of experience and COPD?
- B. What is the current understanding of experience in relation to COPD?
- C. What are the descriptors used in experience to describe living with COPD?
- D. Do the themes and descriptors used in the preliminary PREM-COPD instrument differ to that of the current literature?

2.5.2. Design

Tangible literature was explored in relation to PREMs in COPD, and the current understanding of experience of living with COPD and the language used to describe COPD experience. The literature review design was intended to be broad, to gather work from a number of sources that included studies using the qualitative and quantitative paradigms, while seeking to explore and review new information in relation to COPD and experience. This was undertaken following PRISMA principles. PRISMA is used as an evidence-based systematic approach

to searching the literature and enables a transparent approach to the design (Disler et al., 2012, p. 8).

The individual steps of this review are outlined over the following pages.

2.5.3. Searching and Selection Criteria – Initial Scoping Search

It was also important to narrow the search to patients with COPD to ensure relevance to the study. Probing and reading existing literature enabled the reviewer to identify previous literature relating to other similar concepts such as PROMs and patient satisfaction in the subject field and therefore this enabled a more focused approach on relevant recent published literature in PREMs. Generating an understanding of PREMs in other disease areas enabled the scoping search of PREMs in COPD to focus on the methods and instruments under a PREM heading. There were a number of databases were reviewed and inclusion and exclusion criteria are presented on pp.47-48.

The scoping search strategy included a rigorous search of the following eight computerised databases from 1999 up to May 2013:

1. Allied Medicine and Complementary Database;
2. British Nursing Index;
3. Cumulative Index to Nursing and Allied Health Literature (CINAHL);
4. Embase;
5. Health Management Information Consortium;
6. Health Business Elite Medline;
7. Medline;
8. Psychinfo.

The *Nursing Times* and *Nursing Standard* were also searched to ensure that particular non-specialist nursing journals not included in the British Nursing index were not omitted including a hand search of the literature to ensure a wide range of both clinical and non-clinical journals were captured.

Specific search terms were used and a combination of search terms to ensure a wide range of indexed and non-indexed synonyms was captured. The combination of specific search terms used are shown in Table 2.1. As the terminology of measurement is so varied and the meaning of the measurement of experience is also varied (Health Foundation, 2013), the literature search was extended to include papers specifically on the three main 'measurements of health'; these being outcomes, experience and satisfaction. These are widely used terms within the NHS. Broadly the search strategy included the terms 'patient reported experience', 'outcome', 'satisfaction' AND/OR 'COPD' and other descriptions of COPD as shown in Table 2.1. The word measurement was deliberately omitted due to the construct of measurement which can lead to many different concepts.

Table 2.1
Search terms

Key search words and phrases
Experience
PREM OR PREM_s
PROM OR PROM_s
Patient reported outcome
Patient reported experience
Patient related outcome
Patient related experience
Patient satisfaction
Patient experience
Patient outcome
National health Programmes
NHS
National Health Service
Lung diseases, obstructive
COPD
Pulmonary disease
Respiratory disease

Papers from the scoping exercise were then categorised into the four main themes:

1. Not relating to COPD
2. COPD related but not a measure of experience
3. COPD related on experience but does not measure the experience using an instrument
4. Related to children

Papers were included if:

- they referred to COPD experience and a measurement of experience was recorded;
- the language of publication was English;
- they were published in a journal (no grey literature).

The search for included papers was conducted in May 2013 prior to submission of the project's proposal for ethical approval of this thesis (study two).

A full search outcome is shown in the PRISMA chart Figure 2.3

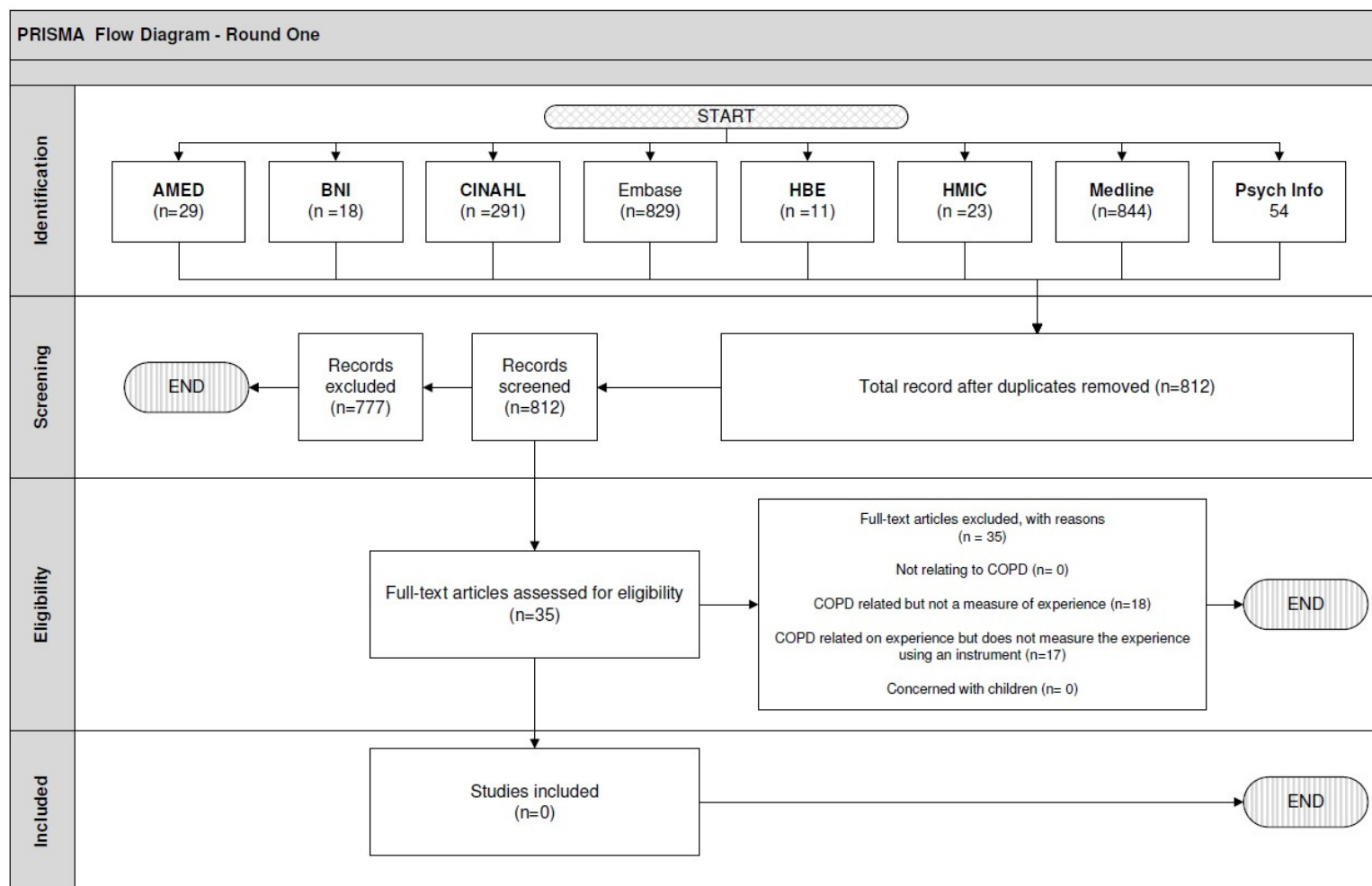


Figure 2.3 PRISMA– Scoping Literature for PREMs in COPD

As the PRISMA flow chart suggests there were no current published papers on the measurement of COPD which described using an instrument to measure patients' experience (objective A). However, it did highlight a number of papers concerned with the recording of people's experience's of living with COPD using qualitative methods of experience descriptors. Therefore a further rigorous search of the literature was undertaken to explore further the meaning of 'experience in COPD' and it's context (objectives B and C). The literature was also then reviewed in relation to the themes and descriptors used to describe experience in COPD from study one on the COPD PREM development (objective C), of which the items and descriptive words were used to formulate the preliminary COPD PREM-38 instrument.

2.6. Main COPD and Experience Search

The scoping search identified a number of papers on the lived 'experience of COPD' but not on its measurement. This main search then focused on ensuring a more recent review of the literature and a manual search of the grey literature was also undertaken. An identical search using the same electronic databases and search terms as in Table 2.1 (p.47) was used. This search was now primarily exploring the patient experience in COPD to include papers on both the qualitative and quantitative paradigms in relation to COPD and experience. The search date was extended from 1990 until July 2014.

This search identified that there had already been two published systematic reviews on the experience of COPD: Giacomini et al., (2012); & Disler et al., (2014). Therefore papers were included if:

- they were qualitative studies that explored the experience of COPD and contained words or descriptors that reflected the experience of living with the disease;
- language of publication was English;
- appeared in the grey literature if applicable to experience of living with COPD, or of healthcare.

Papers were excluded if:

- the paper appeared in the systematic reviews of patient experience by Giacomini et al., (2012); or Disler et al., (2014) over the timeframe;
- the paper measured experience of a specific intervention or treatment in COPD such as palliative care, pulmonary rehabilitation or valve implants (though examples of these would be used within this literature review).

The outline of the rigorous literature review is shown in Figure 2.4 using PRISMA flow chart.

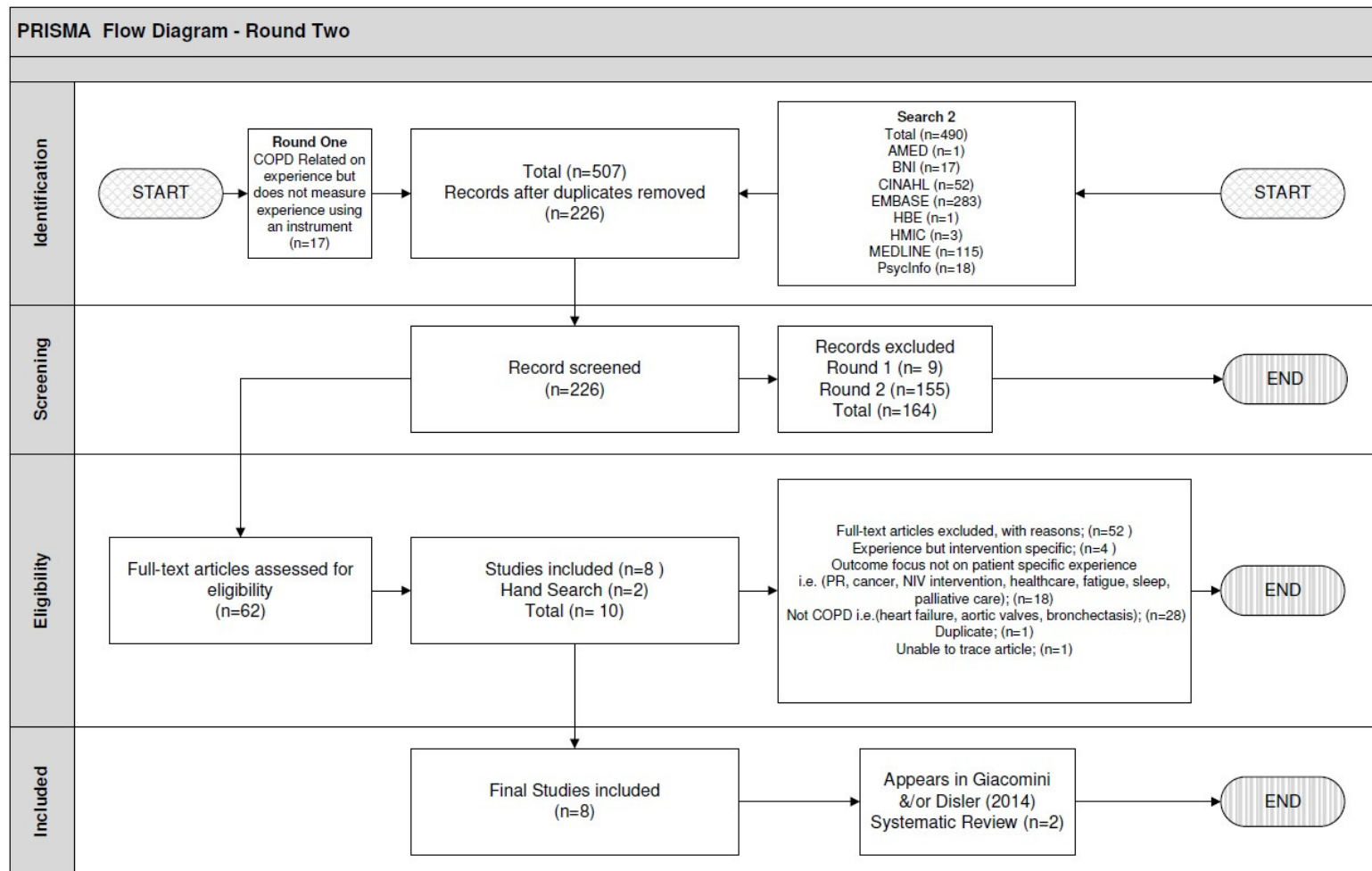


Figure 2.4: PRISMA – rigorous literature experience and COPD search

The results of the computerised search process returned 507 abstracts for review, of which 281 were removed as duplicates. This highlighted 226 records to be screened. When abstracts were reviewed, 164 were excluded for a number of reasons such as 'not COPD', 'not experience' and 'not a discussion on experience'. Initially, to manage the abstracts, including the screening for relevance and suitability according to the articles, they were separated into three groups which comprised: 'review', 'duplicate', and, 'not for review' when applying the inclusion and exclusion criteria outlined on pp.47-48. A total of 62 papers were then identified and fully reviewed. After a further reduction due to relevance to the subject a total of eight papers were included plus the inclusion of the two previously published systematic reviews and the report from Study One by Andrew (2012).

2.6.1. Quality Appraisal

While searching the literature it was apparent the research methodologies were appropriate for this subject matter, many of the articles used qualitative methods exploring different aspects of COPD care in either focus groups or one-to-one interviews. A limitation, however to the scoping review identified that there were a number of papers that did examine patient experience, but these were qualitative designs using interview techniques which did not use any formal 'instruments' to measure experience, only comment on themes generated. Therefore, it was difficult to make any definite conclusions on positive or negative experience as a formal measure of COPD experience. These articles however, were used in the main search to decide on emerging themes and descriptors of experience.

A number of the articles had appeared in peer reviewed journals which suggests there has been some quality checks but adding credibility and an assurance of quality and accuracy a systematic approach to review is critical through appraisal. This is undertaken to enable the evaluation of an article and assess its validity and clinical usefulness (Burns & Grove, 2011). To assist the critical appraisal of the chosen articles identified in this literature review the underpinning principles of the Critical Appraisal Skills Programme tool (CASP, 2006) were used to guide article evaluation. The appraisal tool uses ten questions to help make sense of literature and has been adapted to support literature reviews (Guyatt, 1993, p.2598) and findings are presented in Tables 2.2 and 2.3.

In summary, this rigorous literature review focuses on the literature concerning patient experience in COPD under a number of different themes that focus on the four domains that were highlighted in Study One (COPD PREM development). The current literature on COPD and experience is discussed alongside a presentation of a wide range of additional literature is presented.

2.7. COPD and Experience

An exploratory study by Williams et al. (2007, pp.77-78) emphasised that there had been very limited published research on what really mattered to those people living with COPD, and that research had focussed much more on the reporting of symptoms rather than their impact on living with COPD. However, the lived experience has subsequently been systematically recorded through a number of qualitative means, continuing to focus on the impact of the experience of reported symptoms, daily living, diagnosis, exacerbations and healthcare interventions. Two systematic reviews of qualitative papers (Disler et al., 2014; Giacomini et al., 2012)

were included in this literature review. They were included as they had focussed on systematic searches of the relevant literature in relation to COPD and experiences of living with the disease and of people's experience of healthcare use, over a twelve-year period up until 2012. Both papers have identified a number of correlating themes which have emerged from the literature.

The study by Giacomini, M., et al, (2012) was critiqued using the CASP systematic review tool, of which further details can be found in Appendix Eleven. In summary, this paper was a systematic review of 101 papers and formulated part of a national series of Health Technology Assessments (Giacomini, 2012). The process for systematic review used the GRADE system, which provides a transparent and explicit framework for the judgments involved in quality assessment of papers. It was also subject to external expert peer review. The review had an appropriate research question and used a structured approach to its methodology, with clear inclusion and exclusion criteria. Five themes were identified relevant to the research question and the thematic analysis was robust using two separate reviews. Clear narratives within the themes demonstrated the clear experience of patients and carers of COPD, and the results could be extrapolated across the population. However, the systematic review only reviewed articles written in English and made no attempt to give an overview of the actual studies reviewed, i.e. total number of subjects, severity and/or other patient demographics therefore results were generalised but appropriately documented.

The study by Disler, R., et al, (2014) was also critiqued using the CASP systematic review tool and further analysis is summarised in Appendix Eleven. In reviewing the Disler., et al. (2014) work, the authors undertook a metasynthesis of qualitative research on the experience of advanced COPD. This was an appropriate

methodology to use and explored a breadth of articles relating to the subject matter. Though a research question was not evident, a sound objective with a rigorous search of the literature was undertaken using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). The analysis of the chosen articles were also systematically scrutinised using independent researchers, and the results of the review were narrowed to three clear and focused approaches to living with COPD. Though the review did make reference to this as a limitation of this review, it was a broad generalisation of the term 'advanced COPD'. However, the systematic review was clear, concise and added value to the synthesis of qualitative evidence on living with COPD, which can be generalised to a local population.

These two systematic reviews (Giacomini, M., et al. 2012 and Disler., et al. 2014) were critiqued in this approach as they formulate the main focus to the rigorous literature review, as both identified literature that was historical and highly relevant to COPD experience dating back over a combined 12-year period. As the focus of the thesis, however, was on the 'measurement' of patient reported experience (as identified, there were previously no COPD PREMS) then the further rigorous search of the literature focused on COPD experience themes identified with Study A. These two systematic searches would underpin this literature review as these were two comprehensive reviews already giving rich data which, over this period, had not changed significantly. Critiquing all these papers within these two systematic reviews would have lost focus of the thesis concentrating on the themes of experience rather than its measurement. The findings are summarised in Table 2.2 which gives a clear overview of the study aims, analysis of methods and quality overview.

The remaining eight papers are shown in Table 2.3 which were published between 2012 until July 2014. They were not included in the previous two systematic searches. Table 2.3 gives a clear overview of the study aims, analysis, limitations and quality overview of the papers. The literature identified in Table 2.3 explores more recent published papers focusing on experience and COPD; they were published since the two systematic reviews inclusion dates (objective B). The review will also explore the descriptors used for experience (objective C). And finally it will evaluate any similarities to Study One (COPD PREM development) on the descriptors used to generate the items within the preliminary PREM instruments (objective D) included in Table 2.4.

Table 2.2 Systematic literature reviews of COPD and Experience

Study	Study Aim	Patient Group	Analysis of Methods	Limitations of Study	CASP Evaluation
1. Giacomini et al. (2012)**	To review the empirical qualitative research on the experiences of patients with COPD and informal caregivers from diagnosis to end of life care.	COPD	Qualitative Empirical Literature Search 101 Papers	Large number of articles covering very similar themes Difficult at times to understand the full meaning of the themes as lots of information condensed into small themes.	This was a large qualitative empirical literature search with aim to develop a 'synthesis to relate the findings to the clinical trajectory of COPD care.' A clear research question is presented in this paper, with an excellent range of qualitative descriptors and interpretations of COPD experience through a vast literature search using a number of recognised databases. The empirical systematic review, however, only includes English language reports which may have discriminated some literature given the global prevalence of COPD; it also excludes quantitative research which also poses the question that research which has a mixed method approach would have also been excluded. There was, however, a rigorous process using an expert in COPD to review a final report, but no evidence of any quality assessment used to select articles. The results presented give the reader a clear and good understanding of the needs of the COPD patient's experience and identify clear themes and descriptors for COPD. The results can provide a useful correlation of empirical evidence in COPD across a number of different aspects of a patient's pathway.
2. Disler et	To increase the	COPD	Metasynthesis	Mismatch	The paper is well thought through giving a clear

al. (2014)	understanding of the experience and ongoing needs of individuals living with COPD	22 Articles	between title of study and purpose of it Identified moderate papers but explore advanced disease Missing participant data such as age / FEV1 %	objective to understand the experience and ongoing needs of patients with COPD. The method uses a metasynthesis aimed at generating new insights and understanding of a topic area. However, the objective does not match the title, as the title uses the word 'advanced' but this was only described within the introduction; the characteristics of the majority of papers reviewed suggest that patients had were 'advanced' COPD, however, some papers reviewed do not mention severity, and papers discuss moderate COPD, therefore assumptions been made and generalised within the article. The paper however, does highlight and report on 22 articles in relation to experience of COPD and draws upon trying to generate a 'synthesis' of the literature reported. It has a different context to the previous systematic reviews by challenging the understanding of the varying dimensions of COPD care.
3. Andrew (2012)*	To develop a set if item descriptors to formulate a proposed PREM instrument in COPD	COPD	Report of Study One Qualitative Design (n=89) Discovery Interviews	Missing participant data such as age / FEV1 % A report that was published from the outcome of Study One (COPD PREM development) Identifies four themes and a range of descriptors used to describe the experience of living with COPD. Collaboration project identified in Appendix One.

Table 2.3
CASP overview of experience literature

Study	Study Aim	Patient Group	Analysis of Methods	Limitations of Study highlights	CASP Evaluation
1. Powell et al. (2013)**	To better understand the patient experience of COPD care in order to educate clinicians.	COPD	Qualitative Discussion Focus Groups (n=75)	Not a rigorous research study but written up as one. No ethical consideration or clearance noted Participants' demographics sparse No specific COPD data i.e. FEV ₁ % Participants asked to scale their health on 1-5 (open to wide variation) No clear analysis of	This study had 3 key areas that it wanted to address, but there was not a clear research aim. The paper identifies methods and presents results and discusses them, but this does not demonstrate sufficient rigor in the design process. For example there were no clear methods, research aims or goals, or classification of COPD. Patients were asked to rate their COPD from 1-5 (mean 3.3); however, this type of rating adds no value as it not validated. However, the paper does identify some common themes: there are a number of areas related to people experience in healthcare. However, there is no formal approach to how themes were collated or reviewed, just summaries given. The conclusion however, does identity this as a 'qualitative exercise' for feedback. But overall it provides useful information of people's understanding and experience of living with COPD.

				theme generation	
2. Rocker et al. (2013)**	Understand patients' experiences when opioids are added to usual conventional treatments in advanced COPD patients.	COPD	Longitudinal, observational interventional study (n=44)	Sample group numbers acceptable Possible participant bias as researchers knew sample well Possible placebo effect of drug Results may not necessary be representative of the whole COPD population	This is a very well thought through and well-executed study that really explores the use of opioids in COPD. Though an exact research question wasn't documented, the 'background' gave the reader a good understanding of the aim of the study. A mixed method design, which is appropriate to understanding the experience, as well as objective measurement was a strength of the study, (n=44). The characteristics of the participants were well reported, with a mean FEV1% 26.8 (very severe). The patients however, were well known to the site where the researcher worked, and therefore could have added some sampling bias. This is acknowledged in the limitations as is the small sample group which suggests results are not necessarily representative of the wider population. However, there is only minimal literature or presentation of the previous literature on the subject. Overall a well-structured article adding to the experience data and to the literature on this critical and controversial area.
3. Corcoran	To describe the disease specifics	COPD	Qualitative semi-	Results broad so may not	The aim of the study was clear, using appropriate interview techniques, and the use of QSR Nvivo8

et al (2013)	of patients living with a number of long term conditions	HF Type 2 Diabetes	structured interviews (COPD n=15) (HF=9)	identify as a whole COPD population.	<p>qualitative data software to support results. Although a literature review is not present, an understanding and appreciation of previous literature is acknowledged and well referenced. Characteristics of the participants were acknowledged. However, in the COPD group there was no reference to severity, or even an acknowledgement of how unwell these patients were (i.e. exacerbation history or MRC scale).</p> <p>The results are clearly grouped and good themes identified, however, there is no relation to be made in terms of severity. Therefore, broad results which reported for the 'whole COPD' population rather than a specific group, have been reported using a small sample group, with participants who also have other co-morbidities (though this is acknowledged in the limitations of the study).</p>
4. Lowey et al. (2013)	To describe the experiences and goals for care of patients with end stage HF and COPD who were recently discharged from hospital.	COPD HF	<p>Qualitative descriptive design</p> <p>Semi-structured interviews (n=20)</p>	<p>Population of participants varied</p> <p>No characteristics to determine severity of participants (no FEV₁%)</p>	An appropriate methodology was chosen that sought to find out the experiences of people living with advance COPD, nearing end of life; however, the inclusion criteria for the study was oxygen-dependent, home care with hospital admission, whilst good indicators of advanced disease, no severity or other indicators were included in the inclusion criteria and no use of FEV ₁ % (a marker of severity). However, robust data collection was utilised to determine those nearing end of life. The

				recorded). Indicators of advanced COPD good but not always true.	semi-structured interviews gave a good overview of the key aspects but were not condition specific. The results gave clear themes and identified appropriate themes relevant to the subject.
5. McDonald et al. (2013)	To explore older people's experience of asthma or COPD with reference to their journey in healthcare.	Asthma COPD Both	Qualitative descriptive design Semi-structured interviews (n=21)	Small populations Older population questionable (mean age 68) Gender imbalance Mean FEV ₁ % 51% – therefore matches a moderate picture.	This was a sub study of a larger cross sectional study. A good introduction addresses the question and objective of the study. Gives a rationale for why this was undertaken, and also why people did not take part. A list of questions were used for data collection, appropriate to the initial question asked though a couple may introduce bias into the conversation as they use questions such as 'describe any fears' which influence the direction of the questioning, but open-ended questions were also used. A software package was used to code and categorise potential themes from the data. A good sample size was obtained, though the age range was from 59-82; I wouldn't class 59 as 'older', but the mean age was 68.6. Ethical considerations have been explored and documented. The uses of patient quotes have supported the themes identified. There are concerns however, that the paper examined 3 different lung conditions, but does not specifically address these separately within the paper.

					Therefore, for the reader, it is difficult to understand if this was pertinent to a COPD or asthma patient for example. But overall this paper does add insights and to the growing body of knowledge in respiratory disease.
6. Lindgren et al. (2014)	To illuminate patients' lived experiences of going through the process of being diagnosed with COPD	COPD	Phenomenological-hermeneutic (n=8)	<p>Recruitment of participants varied and therefore results not necessarily representative of the whole COPD population.</p> <p>Wide variation from time of diagnosis of COPD to interview (4 mths-8 yrs).</p> <p>All by 1 participant, a non-smoker</p>	<p>There is a clear 'purpose' proposed but uses the word 'illuminate' which I personally feel is unclear in the context or focus of the study.</p> <p>A phenomenological-hermeneutic analysis was applied to the interviews that were undertaken. This is an appropriate analysis as it sets out to explore and relate to the experiences of a personal significance, in this case the diagnostic process of COPD. The small sample size was acceptable (n=8), all of whom at mild/moderate COPD which was identified in the first stage, but not in the purpose as I feel this study should have been clearer to identify that it was only going to discuss this patient group, as the aim states that a 'variation' of experiences was sought.</p> <p>The study should have explored further people with all severities as this would have added a richer understanding of what it is like to be diagnosed with severe or very severe COPD. However, the narrative and results gives the reader a comprehensive understanding using patient quotes to add richer data to the context,</p>

					giving themes and context. The conclusion of the study also does not match the purpose of the study in terms of informing the reader that there is a better understanding of the lived experiences of patients with COPD at the early stages. This was not the purpose of the study as stated in the abstract.
7. Doos et al. (2014)	To explore the experience of HF and COPD patients and their cares on hospital discharge.	COPD HF	Mixed Methods Questionnaire & Structured interviews (n=14)	Small sample group Saturation of data on discharge Only one area's experience results cannot be generalised No disease-specific experiences noted – broad findings.	This was a mixed methods study which set out clear objectives at the start of the paper exploring the experiences of hospital discharge in patients with COPD and HF. The secondary objectives also made clear. The study suggests the sample was 29 eligible patients, gives justification for 5 pts who didn't complete the survey, and 14 did which equals 19, but there is no record of what happened to the other 10 eligible pts. As participants were also recruited from the same hospital it will be difficult to make the findings broad as this is the experience of one hospital's discharge process. The baseline characteristics give little understanding of the sample group i.e. no record of severity of COPD or HF. However, their analysis of the results and thematic review of the interviews give comprehensive review of the context of the subject answering the objectives set. However I am not sure the questionnaire used in the study adds value to learning about the experience of

					these patients, the questionnaire is more 'satisfaction' based. But overall the qualitative data adds value to this subject area but it would be unwise to make broad judgements from it.
8. Hodson & Andrew (2014)	Review piece discussion on capturing the patient's experience of living with COPD.	COPD	Quality Review Peer reviewed	Not research paper; comment quality piece	This was a peer-reviewed quality piece written to highlight the different aspects of healthcare measurement. The paper addresses a number of different aspects, well written and identifies a need for further specific patient reported measures in COPD.

2.7.1. Living with COPD

Though there is no measurement of patient reported experience in COPD, what has been documented in COPD care is concerned with the description of the measurement of quality of life (Powell, Spranger, Hartl, Roberts, & Fletcher, 2013). It was clear from the introduction that COPD impacts greatly on daily life through difficulties with physical activity and a heavy burden of symptoms, such as breathlessness and cough, with recurrent exacerbations, with some people requiring frequent hospitalisation reported (Annegarn et al., 2012; Janson et al., 2013). Terminology regarding the description of a quality of life measure and a PREM is often confused. However, it has become apparent that measurements of outcomes and satisfaction are also being used to demonstrate a measure of experience. Terminology however to describe this is becoming misunderstood among healthcare professionals as more data emerges in patient experience (M. Hodson, Jennings, & Martin, 2011).

There remain still relatively few studies on the experience of living with COPD despite Giacomini et al., (2012) large empirical literature of experiences of living and dying with COPD. The study examines many themes which were generated from the findings (in Table 2.2) of the review. The study explored COPD from pre-diagnosis through to everyday living and care, including end of life with associated themes with dying. The study clarified that living with COPD, was depressive, with a loss of independence routinely surrounded by the description of 'good and bad days'. Making the most of the good, hibernating in the bad. An alternative approach to exploring living with COPD was by Disler et al., (2014) who focused on a broader meta syntheses interpreting and translating findings from the qualitative studies and integrating or comparing findings, to provide an overview

(Polit & Beck, 2012). Disler et al., (2014) chose to study specifically patients with 'advanced COPD'. But the paper title suggests that advanced COPD is the focus, but gives no real clear definition of the description of this until much later in the paper. This paper also themes in connection with living with COPD and identifies similar themes to the previous Giacomini et al., (2012) paper highlighting specific aspects of COPD care such as activities of daily living and describes the heavy burden of symptoms, as key sub- themes within living with COPD.

To generate a better understanding of the themes and descriptors used in these papers and to describe the aspects of experience clearer in these two papers. The themes were mapped against Disler and Giacomini reviews and the data reported from Study One (COPD PREM Development) (Andrew, (2012). This gives an overarching overview of the common experience themes and descriptors of experience used within these three main studies to describe the overall experience of living with COPD, including emerging experience themes and descriptors of experience outlined in Table 2.4.

Table 2.4
Summary of the three studies and their descriptors in COPD

Article	Theme	Sub-theme	Descriptors
Giacomini et al. (2012)¹	Experiences of diagnosis	<ul style="list-style-type: none"> - Normal way of life ^{2,3} - Limitations due to smoking or aging - Seek help for acute event not chronic - Not communicate a diagnosis clearly - Information in stages - Poor information and education ² 	<ul style="list-style-type: none"> Worry ² Normal Interpret mistakenly Incurable / fatal information ^{2,3} Communication ³ Unaware

	Smoking	<ul style="list-style-type: none"> - Different beliefs - Other exposures - Cause of COPD - Shame and self-blame 	Not enough Guilt Shame Regret Self-blame ^{2,3} Stigma
	Experience of daily life ^{2,3}	<ul style="list-style-type: none"> - Good and bad days - Breathlessness and symptoms ^{2,3} - Activities of daily living affected ² - Depression ^{2,3} - Episodic emotions - Hospitalisation - Loss of independence ² - Multidimensional <p>Relationships with others</p> <p>Challenges of smoking cessation</p> <ul style="list-style-type: none"> - Complex - Understanding ve-/ +ve benefits <p>Interactions with the healthcare system³</p> <ul style="list-style-type: none"> - Poor relationships - Access poor 	Exhausting Struggle Fatigue ^{2,3} Loss of enjoyment Fear ^{2,3} Panic ^{2,3} Dread Struggle Relationships Anger ^{2,3} Frustration ^{2,3} Disruption ^{2,3} Hastiness Compassion (lack of) Invisible Isolation
	Experiences of exacerbations ³	<p>Recognition</p> <ul style="list-style-type: none"> - Acute in nature <p>Treatment</p> <ul style="list-style-type: none"> - Management of one - Role of the HCP / Patient relationship <p>Recovery</p> <ul style="list-style-type: none"> - What does future hold 	Terrifying Acute Sudden death Recovery Frightening ³ Terrified Distrust Uncertainty ³ Prognosis ^{2,3} Significance (of health)

	Experiences of the end of life	<p>Understanding the prognosis of COPD</p> <p>Experience of dying</p> <ul style="list-style-type: none"> - Take over every aspect of life - Daily challenge of living <p>Communication with healthcare providers</p> <p>Palliative Care</p> <ul style="list-style-type: none"> - language used by HCPs - lack of a definition among HCPs 	<p>Fatal</p> <p>Uncertainty</p> <p>Poor</p> <p>Lack of understanding ²</p> <p>Death</p> <p>Social Isolation ²</p> <p>Imminent</p> <p>Suffocating</p> <p>Final attack</p> <p>Language</p> <p>Breathlessness ^{2,3}</p> <p>Hope (dashing of) ²</p>
Disler et al. (2014)	<p>Better understanding of the condition</p> <p>Sustained symptom burden</p> <p>Unrelenting psychological impact of living with COPD</p>	<p>Breathlessness</p> <p>Fatigue</p> <p>Frailty</p> <p>Anxiety</p> <p>Social isolation</p> <p>Loss of hope</p> <p>Maintaining meaning</p>	<p>Debilitating</p> <p>Exhausted</p> <p>Frailty</p> <p>Hope (loss of)</p>
Andrew (2012)	<p>Journey to diagnosis</p> <p>Usual care</p> <p>Exacerbation</p> <p>My everyday life</p> <p>Hospital</p>	<p>The limitations of living with COPD</p> <p>Going to hospital</p> <p>On arrival to hospital</p> <p>On the ward</p> <p>Discharge from hospital</p> <p>Follow-up care</p>	<p>Shocked</p> <p>Frightened</p> <p>Frustrated</p> <p>Surprised</p> <p>Annoyed</p> <p>Confused</p> <p>Angry</p> <p>Embarrassing</p> <p>Motivated</p> <p>Gratitude /</p> <p>Respect</p> <p>Worry/ fear/ unknown</p>

1 Giacomini et al. (2012)

2 Disler et al. (2014)

3 Andrew (2012)* Report from Study One findings (in development for publication)

Within the three studies there are a number of similarities used to support the development of items and descriptors in Study One (COPD PREM development). This is partly due to the fact that both Disler and Giacomini review many of the same papers, though Disler makes greater use of experience descriptors and 'quotes' from papers reviewed to describe meaning behind themes, whereas Giacomini explores developing the themes and draws on a variety of papers and sources, so descriptive words are used but the literature source for these words is unclear. But what is evident is that the COPD journey is unclear and the pathway is complex with a mixture of conceptual descriptors which are common on both the positive (happy, respect, gratitude) to subjective poor (frightened, fear, shocked) descriptors, clearly stressing that living with COPD has a massive impact from diagnosis to end of life.

The subsequent discussion of this literature review will fall under the four main themes identified within the thematic review of Study One (COPD PREM Development) which includes:

1. History and COPD;
2. Usual care in COPD;
3. Everyday life with COPD;
4. COPD exacerbations.

These four themes are identified in relation to describing the experiences documented through the whole COPD pathway.

2.7.2. History and COPD

Several studies have recorded specifically the COPD experience and history of obtaining a diagnosis of COPD, and it is widely reported (Arne, Emtner, Janson,

& Wilde-Larsson, 2007; Pinnock et al., 2011). Common themes suggest prior to a diagnosis symptoms were a part of everyday life, or attributed to aging or smoking (Giacomini et al., 2012). The descriptive data published by Disler et al., (2014) highlight a number of key points in examining what has previously been published (between 1990 and 2012) on understanding the experience of COPD. These themes are resonant with much of what the literature from the Giacomini review also expressed, especially surrounding the understanding of the disease and its diagnosis. Many people did not know that COPD is a long term condition, or understand alien terms and language used, for instance, in terms of there being no cure and the experience of how the doctor or nurse would talk about the disease. Common descriptors highlighting experience included 'conflict', 'fear' 'regretted' and related to people's own lived experience through the context of an event or expressed through everyday life.

A further study, specifically on the negotiation of the diagnostic process by Lindgren et al., (2014, pp.441-445) used a phenomenological-hermeneutic analysis, which enables the research to approach the interviews with no prior-judgement or understanding of the phenomena and the interview description of (n=8) mild to moderate COPD would argue that this was the case. Patients were interviewed about their experiences of being in the diagnostic process of COPD, although a small study. Lindgren et al., (2014, p.441) affirmed that the diagnosis of the disease in this study for participants that was 'prolonged' and 'unclear' with three themes being identified: 'living with a body out of step with the diagnosis'; 'dealing with the past'; and 'being challenged by the future' with descriptors used by participants such as 'scared', and 'unaware'. Though descriptors used in these studies were similar in Study One (Andrew 2012), there were a number who used

additional terms such as 'shocked', 'surprised' and 'annoyed' as descriptors of getting a diagnosis which were not highlighted in previous studies (Disler et al., 2014).

Making sense of the diagnosis and the way this is communicated is a fundamental part of the journey of living with COPD. However, the Lindgren et al. (2014) study only explores experience of patients with mild to moderate COPD ranging from 4 months to 8 years from diagnosis to interview. There is also no distinction between the time of diagnosis and experiences being recorded. It was also evident in the Disler, (2014) and Giacomini, (2012) systematic reviews that no real distinction between the categories of severity of the disease were made, thereby at times giving a broad overview of experience in the diagnostic phase which potentially, should not be generalised to the whole COPD population. What is clear from the literature is the need to have an understanding of negotiation during the diagnosis phase, where people shift to an acceptance and accepting phase. Information and experience are key in the delivery of the critical messages of diagnosis. This was supported by the Giacomini et al., (2012, p.11) review and synthesis of the qualitative empirical literature that highlighted a number of different experience themes which will continue to be discussed throughout this chapter. 'Receiving a diagnosis' was also a key theme, highlighting miscommunication with diagnosis often 'given in stages as medical events arose'. A recent large retrospective study (n=38,859) published in the Lancet by Jones et al., (2014, p.267) stressed the missed potential in COPD diagnosis as reported by patients' negative experiences. The data presented suggested that opportunities for diagnosis were missed in 85% of patients' clinical notes reviewed within the five years immediately preceding a final diagnosis of COPD. This data was

undertaken using primary care records. This supports the qualitative literature of the poor experiences of people getting a diagnosis right in the first instance.

2.7.3. Usual care in COPD

Information needs are an essential component to any long term condition. This is not just essential at diagnosis, but must be ongoing to ensure that patients, once diagnosed, understand their condition and how to manage it. Disler et al., (2014, p.17) emphasis that 'loss of hope and meaningless in life' are important concepts for healthcare professionals to maintain engagement in self-management techniques. The relationships that patients build with healthcare professionals are fundamental to the experiences of patients with COPD adhere to usual care. A quantitative study of 15 COPD patients by Corcoran et al., (2013, p.19) maintains throughout their paper on the experiences of patients with long term conditions, that understanding experiences associated with COPD will enable healthcare to tailor specific services. The study also highlighted that interaction with general practice is time limited and this interaction also emerged as a theme in the Giacomini et al., (2012, p.18) paper too. In essence, communication with healthcare professionals is key but Andrew, (2012, p.6) study highlights that patients are sometimes the 'poor relation'. And a poor relationship with healthcare professionals has led to descriptors such as 'frustration' 'confusion' and 'control (lack of)' when discussing areas such as medication or conflicting information about the disease itself. These however are the same descriptors used in the diagnosis phase as previously described. Powell et al., (2013, p.353) claims that a flip side of communication is expressed in a positive experience when staff are knowledgeable and sufficient, descriptors used to describe the effect of this were 'it reduces anxiety' and 'alleviates fear' There are additional responses by Andrew

et al., (2012, p.14) who advocates a positive experience from various healthcare professionals (physiotherapist/GP/nurse). Reporting that there is mutual respect when you are listened too but a sense of 'frustration' when you are not. Frustration was a common descriptor used in describing many aspects of COPD experience either by symptoms or the impact of living with the symptoms associated with the disease. Andrew, (2012, p.16) also stresses that in 'usual care' the descriptors 'enjoyment' and 'self-gratitude' are also key in the management of care and relationships with healthcare professionals. It is must be noted that these positive descriptive terms are not reported in either the Disler or Giacomini papers, potentially introducing a bias in only reporting the negative experiences of patients with COPD.

2.7.4. Everyday life with COPD

The experiences of patients everyday life with COPD were captured in both systematic reviews as well as the other main papers (Doos et al., 2014; Lowey, Norton, Quinn, & Quill., 2013; Powell et al., 2013). Disler et al., (2014, pp10-11) describes that everyday life is focused on the burden of symptoms such as 'breathlessness, fatigue resulting on reduced physical activity' which impacts on daily life. Giacomini et al., (2012, p.11), draws from the literature that everyday life is fundamental to the 'whole ethos of understanding the patient journey'. Once a COPD diagnosis had been made, life changes and many people reported that the experience of living with the troublesome burden of symptoms, as previously described as 'frightening', 'exhausting' and filled with 'fear'. Three common descriptors are used to describe daily life experience in patients in both reviews.

A later paper, as part of a larger study, by Corcoran et al., (2013) exploring experiences of several long-term conditions, examined 15 participants' experience of living with COPD using semi-structured interviews. The results suggested that those interviewed were 'angry about the limitations' it forced on their life. With one third of participants signifying they pushed themselves to the limits. The feelings of 'being angry and frustrated' were also commonly reported. However, once again the authors do not indicate the severity of lung disease, either by measurement through spirometry or on a scale rating. Therefore it continues to be difficult to know whether these results can be extrapolated to the whole COPD population. But words such as 'frustration' and 'exhaustion' were similar descriptors to those described by participants in Study One (COPD PREM development).

A further paper by Powell et al., (2013) showing a European perspective of COPD participants (n=75) with an average length of time living with COPD of 15 yrs, used table discussion and a series of questions to inform discussion around the experience of living with COPD and its effects on daily life. The group provided a number of insightful experiences which covered the four main key themes previously identified. Key recommendations of the study were 'different methods of assessment' needed, and 'treatments' and future care needs to be 'individualised'. The limitations on daily life were also a key theme identified across the whole group and are this was also explored further by Lowey et al., (2013) who explored the experiences of people (n=10) living with advanced COPD, using a qualitative descriptive research design. However, the severity of the participants were not disclosed, within the inclusion criteria participants had to be a current 'home care patient' and 'oxygen dependent', mean age 73. This suggesting that the description of severity in this study was based on activity and oxygen rather than

FEV₁%. Lowey et al., (2013, p.353) propose descriptors of experience to include difficult symptoms, such as 'shortness of breath' as 'frightening' and 'acceptance'.

It is apparent from the studies mentioned that the experience of participants describe and articulate powerful words which are used to describe living with the disease, based on a 'lived experience' of the disease. Their experiences of the severity of symptoms: 'what was yesterday like?' or from their last exacerbation (worsening of symptoms) echo and impact greatly on personal experiences connected by the disease itself. These further studies (Lowey et al., 2013; Powell et al., 2013) have supported the previous work on the experiences and descriptors of living with COPD and its impact on everyday life.

2.7.5. COPD exacerbations

It is evident that COPD exacerbations or flare-ups, a worsening of respiratory symptoms which can be infective or non-infective in presentation (Trappenburg et al., 2011, p.43) are a common occurrence for some patients, causing a sudden worsening of a person's reported normal day-to-day symptoms such as an acute worsening of breathlessness and increase in cough and sputum and in many cases the need for intervention (antibiotics and steroid tablets) and or hospitalisation (Arostegui et al., 2014; Osthoff & Leuppi., 2010; Pauwels & Rabe, 2004). Alongside the reported increase in acute breathlessness and reduced activity, impacting greatly on quality of life, exacerbations are one of the most reported experiences documented (Disler et al., 2012; Mikelsons & Wedzicha, 2009). Both Andrew, (2012) and Giacomini et al., (2012) report on the experiences of patients in acute exacerbation as 'advancing disease'. The recognition of an exacerbation and the severity of its symptoms is, in some patients, difficult to

predict and the introduction of phenotypes could predict patterns in COPD exacerbations (Han et al., 2010).

Recognising the symptoms and access to quick treatment or primary healthcare are potential barriers to poor experience in exacerbations. The descriptive terms included with the literature summarised as 'frustration' 'annoyance' or 'confusion' over when to start medications or conflict of whether this was 'just another bad day'. The descriptors, however, were similar throughout the literature, except Disler et al., (2014) does not discuss exacerbations as a major or sub theme of experience in the study, but make reference only by suggesting an increase in exacerbations which is a non prognostic indicator of advancing COPD.

The relationships and communication with healthcare professionals continues to be a major factor in the experience of an exacerbation. The expert advice or the need for 'reassurance' can be a key factor in both a positive and negative aspect of an experience. It is interesting that reassurance was not commented on as a descriptor in either of the two systematic reviews but was a key term used by Andrew et al., (2012). Patients seek reassurance especially in times of increased vulnerability such as an exacerbation. This is supported by the work by Lowey et al., (2013, p.355) which is suggesting that 'COPD patients live in a cycle of intermittent exacerbations'. This recent qualitative descriptive research design also explored the current experiences of advanced COPD patients. Exacerbations were again predominant in the findings, with people describing them as 'bouncing back (from an exacerbation)' and using descriptors such as 'declining health' though professional relationships were less intrusively discussed but communication was key using descriptors such as 'inaccuracies (of the diagnosis)'

were used. The experience of exacerbations can clearly be varied but are described by similar experience descriptors as previously mentioned.

2.7.6. COPD and the hospital

The severity of acute exacerbations of COPD were also entwined within a much wider picture for some patients presenting to hospital either as an acute admission to the emergency department for assessment, and in the majority, a subsequent admission and period in hospital. Kessler et al., (2006, p.133-136) used a cross-sectional study (n=125; mean FEV₁% 40.9% predicted) and advocates that the frequency of exacerbations in patients living with COPD 'have an average of four to five exacerbations per year requiring some form of treatment or hospitalization'. This time many patients felt or expressed fears of an increase in dyspnoea associated leading to 'worry' and 'embarrassment' highlighted in Andrew et al., (2012, p.17). Due to the increase in symptoms and the need for additional treatments, 'uncertainty' was a common descriptor used not only to describe current health but also the 'future' or limitations another exacerbation may have on their future health. The Giacomini et al., (2012, pp.22-29) review gave a clearer emphasis on 'what the future held' and used descriptors such as 'prognosis' whereas Andrew et al., (2012, p.23) would argue that patients needed a very clear exacerbation pathway from pre-hospital decisions to discharge planning which wasn't dissimilar to previous, but less emphasis on the future as outlined in Table 2.2. Both papers, however, make reference to the 'hospital discharge' following an exacerbation where the levels of 'uncertainty' grew in 'new aspects' such the prognosis and recovery time and others regarding everyday aspects such as 'frustration' of waiting for medications.

A mixed methods approach to collecting data through interviews and a survey by Doos et al., (2014) with a small COPD sample (n=5) on the experience of patients on hospital discharge transition from hospital with COPD and Heart Failure (HF) also conclude that 'medication and clarity of information on diagnosis' was limited and the ongoing need of care descriptors of their experience 'confusing' and 'vague', as previously similarly recorded. However, a limitation of this particular study is the number of participants (n=5), which is a small population. This is acknowledged by the author who suggests that they reached 'no new theoretical insights' and therefore may not be an illustration of the total COPD and HF population. It is evident, however, that the Doos et al., (2014) study does add to the additional body of knowledge and that COPD as a disease is made more complex by the impact of significantly co-morbidities (Areias, Carreira, Anciães, Pinto, & Bárbara, 2014; Burgel et al., 2013; van der Molen, 2010), impacting and adding to the negative experience of patients leaving hospital after an exacerbation of COPD with or without HF.

2.7.7. Symptom Burden

The burden of different symptoms associated with COPD is complex and varied (Tödt et al., 2014, p.1) even between the assessment of patient and healthcare professional. An interesting observational, cross-sectional, descriptive study completed by Miravittles et al., (2013) with a total of 450 COPD patients investigated ten symptom items based on ranking by patient and healthcare professionals (Figure 2.5). The three most common perceived symptoms were

breathlessness, cough and fatigue which were matched by the patient and physician and the remaining seven items coincided by 52% (Figure 2.5).

	Patient's assessment		Physician's assessment		Spearman's Rho	Difference in means ^b
	Position in the ranking	Mean (SD)	Position in the ranking	Mean (SD)		
Breathlessness/shortness of breath upon exertion	1st	2.58 (1.04)	1st	3.05 (1.34)	0.29	<0.001
Fatigue, tiredness, lack of energy in general	2nd	2.23 (1.15)	2nd	1.67 (1.46)	0.30	<0.001
Coughing	3rd	1.81 (1.11)	3rd	1.53 (1.41)	0.29	<0.001
Anxiety/nervousness	4th	1.57 (1.27)	7th	0.49 (1.03)	0.34	<0.001
Expectoration	5th	1.56 (1.09)	4th	1.05 (1.28)	0.36	<0.001
Dry mouth	6th	1.45 (1.32)	9th	0.35 (0.94)	0.27	<0.001
Despondency, sadness or enervation	7th	1.43 (1.24)	5th	0.63 (1.13)	0.36	<0.001
Wheezing/whistling in the lungs	8th	1.32 (1.07)	6th	0.54 (1.03)	0.25	<0.001
Difficulty sleeping, sleep disorders	9th	1.32 (1.25)	8th	0.39 (0.90)	0.33	<0.001
Chest pain	10th	0.71 (0.95)	10th	0.19 (0.66)	0.28	<0.001

^a The scale used ranges from 0 (doesn't affect/concern the patient) to 4 (affects or concerns the patient a lot).
^b After conducting the Kolmogorov–Smirnov test a comparative analysis by means of non-parametric tests was conducted: test for 2 independent samples *U* Mann Whitney (confidence level of 95%).

Figure 2.5 Ranking of COPD symptoms, Miravittles et al., (2013, p.1980).

It is evident from this study that, like experience, the perception of symptoms can also be portrayed differently. Therefore access to professional healthcare can also support variation in people's experience from the patient's perspective and that of the healthcare professional if we can match symptoms effectively. However, there are a number of limitations to this study. Therefore results need to be observed with caution: within the patient characteristics, such as a gender imbalance with 91% being male and the questionnaire used to range the symptoms was not formally validated and not tested for validity or reliability in such a research setting. Miravittles et al., (2013, p.1981) argue not only the complex issues of symptoms but also three main symptoms which were also very apparent in the systematic reviews as key symptom experiences in the burden of COPD these being breathlessness/dyspnoea, fatigue/tidiness and cough.

2.7.8. Breathlessness/dyspnoea

The most-reported theme expressed throughout the different themes and aspects of COPD care and experiences is the reported heavy burden that the symptoms of COPD place upon those diagnosed with the disease. Disler et al. (2014) and Giacomini et al. (2012) make significant reference to the burden of symptoms and living with these. Breathlessness and its major impact in quality of life has been reported extensively (DiBonaventura et al., 2012; Pauwels & Rabe, 2004). It was also a descriptor used in all the themes identified in both the systematic reviews, with associated descriptors such as 'worsening', 'acute' or 'breathlessness' and the feeling of 'suffocation'. This was also highlighted significantly in the exacerbation theme and as the most commonly reported experience symptom in obtaining a diagnosis or seeking help in an acute episode pre-diagnosis. The association of breathlessness and reduced physical activity is also another common thread in COPD reporting, breathlessness being a major concern for a 'reduction (in), or worsening (of) activity'. This can be in both the acute, chronic and progressive stage of the disease. The association of breathlessness and end of Life care is also widely reported in the literature with descriptors such as 'social isolation' and 'imminent death' associated with a poor experience (Disler et al., 2014; Hodson et al., 2013).

2.7.9. Fatigue

Fatigue was a sub-theme of the sustained symptom burdens highlighted by Disler et al., (2014, p 2) who recommends that fatigue is an altered behaviour and causes frustration which leads to changes in routine and changes in everyday life. Certainly, the descriptor of 'frustration' was a common theme identified in the

systematic reviews, along with synonyms of this such as 'annoyance' and 'irritation'. A Stage One instrument development on the measurement of fatigue in COPD by Trendall & Esmond (2007, p.116) reports on the measurement of fatigue to be used by nurses to measure a level of fatigue. Trendall and Esmond (2007, p.118) identified a number of aspects in the measurement of this and the impact this has on daily life. One key finding of this development was the associated between fatigue and its relationship to breathlessness.

2.7.10. Cough

The management of cough in COPD over the last 40 years has received very little attention (Calverley, 2013, p.245), despite it being one of the most reported symptoms in COPD and playing an important role in the quality of life that patients reported as being a key burden of living with the disease. Cough, for many, has not been explored or assessed fully but the implementation of new measurements such as the COPD Assessment Test focuses on the question of cough (Figure 2.6)

The image shows the user interface of the COPD Assessment Test (CAT). At the top, there are two input fields: 'Your name:' and 'Today's date:'. To the right of these fields is the CAT logo, which consists of a green speech bubble containing the letters 'CAT' in blue, with the text 'COPD Assessment Test' underneath. Below the input fields, the title 'How is your COPD? Take the COPD Assessment Test™ (CAT)' is displayed in blue. A paragraph of text explains the purpose of the questionnaire: 'This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.' Another paragraph provides instructions: 'For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.' An example is given: 'Example: I am very happy' followed by a row of six circles containing the numbers 0, 1, 2, 3, 4, and 5. A large 'X' is placed over the circle containing the number 2. To the right of the circles is the text 'I am very sad'. Below this example, there is a question: 'I never cough' followed by a row of six circles containing the numbers 0, 1, 2, 3, 4, and 5. To the right of the circles is the text 'I cough all the time'. To the right of the question and response options is a box labeled 'SCORE' with a downward-pointing arrow.

Figure 2.6 COPD Assessment Test (CAT)

The need to refocus and discuss cough has become more apparent in clinical consultation.

2.7.11. Smoking

Smoking is a further theme that is intertwined through the different aspects of experience from experiences of stopping smoking, impact on smoking, not wanting to stop smoking, and information needs on smoking. Descriptors which described smoking in the context of experience included 'self-blame', 'annoyance' and 'scared'. Smoking was identified within all of the systematic reviews, but with a greater emphasis on the review by Giacomini et al., (2012) who suggest that smoking and advice to quit respond in different ways was similar to the findings Andrew, (2012). One comment from a patient suggested the 'lack of understanding of the acceleration of smoking and its impact on COPD, knew it was 'bad' to smoke, but continued to do so. Descriptors included 'complicated' but others suggested it brought 'pleasure' and 'comfort'. A longitudinal study of smokers by Fidler & West, (2011) (n=2257), not COPD specific, looked at smokers and quit attempts support this reasoning behind not stopping. The results suggested such enjoyment of smoking is an opposing argument in people who decide to carry on smoking despite awareness of the dangers (Disler et al., 2014).

2.7.12. Healthcare

The experience of healthcare has been written about extensively and much of the change currently happening within the NHS for example is a direct response to the collection and greater understanding of the experience of patients' use of healthcare. Experience of healthcare can generally be categorised into two fields: First, the experience of patients and the 'health service' and their use of services

within the NHS and that of 'healthcare professionals', and, second, patients' experience of meeting healthcare professionals from a general practitioner to the COPD clinical nurse specialist. Giacomini et al., (2012, p.20) suggests that patients with COPD have a varied and often poor connection with healthcare and those that provide healthcare, with patients using words such as 'poor listening' or 'lack of compassion', describing themselves as seeming 'invisible to clinicians'. The review clearly highlights that patients with COPD are cut off from healthcare due to many reasons such as social isolation, continuity of care and logistical issues to do with visiting healthcare services due to lack of mobility, breathlessness and oxygen therapy. This is supported further by Corcoran et al., (2013, p.19) signifying that previous literature (Belfer & Reardon, 2009) highlight that basic activities can be strenuous and daunting, but this is changing. Corcoran et al. identified that one-third of patients in their study (n=5) reported engaging in physical activity. However, these results need to be taken with caution as due to the small sample group results cannot be generalised to all COPD patients. Disler et al., (2014) continue to focus on the healthcare professional and patient experience and was more on the downbeat aspects of information giving in areas such as smoking cessation and end of life care. One participant was quoted as saying (Disler et al 2014, p.11)

The doctors, the nurses, especially Dr [name], he'd have an idea how long I'm going to last, but I don't want to know, not bothered.

Important aspects of information giving are fundamental to supporting patients with COPD. Disler et al., (2014, pp.10-12), makes it clear that the lack of discussion in many aspects of the patients' journey impacts directly on patients experience of healthcare. The descriptors used for this impact included 'decline', 'we don't

discuss' with key healthcare professionals and a focus on the general practitioner. This was evident in both systematic views that the GP's or physicians were important key providers of care, and thus a positive experience of their interaction was critical.

A discussion paper by Powell et al., (2013) set in Europe suggests that the focus groups and discussion on information provision should be through the 'doctor', but recognised the fact that time and contradictory advice were often some of the pitfalls to providing information about COPD. Therefore these two issues provide patients with a poorer experience of healthcare and those providing it. A further study by McDonald et al., (2013, pp.497-498) specifically explored the insight into older people (mean age 68, but range from 59-82, it has to be questionable if 59 is old) but the healthcare experiences with managing COPD, using qualitative interviews (n=21) also identified the themes of 'not being heard or recognised' which impacts on experience not being involved in care as a collaboration. The paper fails to identify if it was specific healthcare identifying it as the 'healthcare team', but throughout the paper the GP is identified as a key healthcare provider. But negative experiences were highlighted which include 'did not get heard by her GP' with several participants identifying a lack of confidence in their GP. Information was a key factor in the delivery and understanding of the future outlook and understanding of COPD with confusion on diagnosis but always delivered by a healthcare professional. The Lindgren et al., (2014, p.441) paper on the patients' experience of the diagnostic process of COPD claims that a diagnosis should be made with empathy, time and to allow patients to share stories, with good communication which is fundamental for understanding. However, it is evident that there is a wash of negative

experience impacting on people's experience of healthcare and that of healthcare professionals with many participants involved in these studies citing experience, time, lack of understanding and compassion for this long-term condition called COPD, the C being 'chronic' and not cancer as cited by one participant in the Disler et al., (2014) review.

2.7.13. Interventions and Experience

A 'potential' third arm of healthcare experience is that of interventions usually provided or recommended by healthcare professionals. This systematic review discussed throughout these sections included other studies (Corcoran et al., 2013; Rocker et al., 2013) that have also all focussed on particular aspects of the journey of COPD from pre-diagnosis through to and touching on end of life care in COPD along with the different recorded descriptors of patients experience through this journey. Many articles were not included as they focussed on specific detailed areas such as end of life care or advanced disease and other invasive interventions such as valve insertion or transplant. There are however, a number of specific interventions that are discussed over the next few pages as experience is highly reported in the literature with regards to two specific interventions and are not included in the selected two systematic reviews (Disler et al., 2014; Giacomini et al., 2012). These are the use of opioids and pulmonary rehabilitation, two issues which were highlighted in the Andrew, (2012) Study One (COPD PREM development).

2.7.14. Opioid Use

The use of opioids in COPD is increasing to support patients in breathlessness management (NICE 2010). However, there are limitations to this as we have for

more than twenty years known that in COPD morphine has supported a reduction in dyspnoea with little attention been given to this (Rocker et al., 2013, p.27). A qualitative study was undertaken by Rocker et al., (2013) of 44 patients (mean age 74) participating in a 6-month trial of opioid therapy for refractory breathlessness. This trial was to understand patients' experiences of opioids and used semi-structured interviews and other health-related QoL measures to document these experiences. Rocker et al., (2013, p.27) as 'I'm feeling 100% better than I did before', and negative experiences such as 'I couldn't feel anything at all in the line of difference'. Lowey et al., (2013, p.356) describe the experience of the trade-offs with living with advanced COPD suggesting that patients would accept interventions such as non-invasive ventilation, in order to reduce hospital utilisation common with COPD patients and exacerbations. Rocker et al., (2013 pp.34-35) claim that using opioids for refractory dyspnoea in participants suggest this is an 'acceptable intervention for advanced breathlessness and patients experienced improved symptoms'.

2.7.15. Pulmonary Rehabilitation (PR)

Pulmonary Rehabilitation has long been seen as the gold standard for patients which consists of between 6-8 weeks of supervised exercise and an education programme aimed at improving quality of life by the better management of symptoms and an understanding of the lung condition (Lacasse, Martin, Lasserson, & Goldstein, 2007). This is normally delivered by specialist nurses and physiotherapists who are trained and have the expert knowledge of respiratory disease (Nici, Lareau, & ZuWallack, 2010, p.655). There has been much written about PR which was excluded from this systematic review. However people's experience of PR has been summarised by a systematic review of qualitative

research by de Sousa Pinto et al, (2013, p.141) who argue that there was a sense of increased well-being and health promotion summarised by an increased 'way of life'. The Disler et al. (2014) review, however, made very little reference to PR except that one participant suggested that for the first time, we [participants of PR] were not going to cure or reverse COPD, again reflecting on the information needs previously mentioned. The advert that PR groups are delivered by specialist respiratory teams highlight the important impact on greater specialist knowledge.

2.7.16. Long Term Oxygen Therapy

Previous work by Clancy et al. (2009) was not part of the systematic search, but was already identified in the Giacomini et al. (2012) review, specifically in relation to COPD patients (n=10) and the use of long-term oxygen therapy. This longitudinal 'Heiddeggerian' study explored the experiences over time of which the conclusion demonstrated that oxygen had a negative effect on quality of life and lifestyle with descriptors used such as 'blame' and 'fear' saturating many of the descriptors previously presented in other aspects of COPD care. This is one example which suggests descriptors of experience can be interchanged and used as a negative or positive affirmative to experience (Roberts et al., 2012).

2.8. Conclusion

This chapter has given a comprehensive overview of the diverse aspects of experience in both health and business touching on the concepts of experience and satisfaction and the blurred understanding of these in practice. The systematic review concluded that there was currently no published instrument available to clinicians to measure experience in COPD. However, there is a plethora of clear literature that describes the experience of living with the disease and descriptors

that have been highlighted to describe many different aspects and interventions of the disease pathway from pre-diagnosis to end of life care. The literature also informed that the measurement of and collection of experience is fundamental to the quality (NICE, 2012) of healthcare but should not be measured in isolation (Robert & Cornwell, 2013). The introduction of the patient experience framework (NHS Institute for Innovation and Improvement [NHSIQ], 2003) gives an overarching contextual understanding of the principles needed to ensure quality patient experience by having these principles guide services to develop and ensure high quality patient-centred care. This is critical when ensuring the development of a new instrument. However this literature review has only touched on some of the key important messages in COPD and experience; intervention and other specific aspects of COPD care have not been discussed.

The understanding of PROMs which have become routine clinical practice, and the use of PREMs is relatively new (Hodson et al., 2013). Therefore, Chapter Three will give the reader an appreciation of why and what we are measuring in healthcare and its important aspect and place in healthcare to ensure that quality care is being commissioned, measured and delivered to all. Collecting patient data in healthcare is evident in many forms such as patient reported outcome measures, Quality of Life and Assessment all of which will be summarised in Chapter Three.

The experiences expressed by this rigorous literature review were similar to the thematic analysis that took place in Study One (COPD PREM development) as outlined in the themes and descriptors in Tables 2.3 and 2.4 suggesting the widespread qualitative literature available supports the descriptors and items

generated within each of the 4 themes for the preliminary COPD PREM-38 instrument.

CHAPTER THREE

CHAPTER THREE

3. Measuring Healthcare through Instruments

3.1. Introduction

The introduction to the literature review in Chapter Two gave a concise overview of what it meant by experience, how it is defined and also how experience is intertwined with many of the fundamental business values that we ourselves experience as customers and as users of the health service as patients. The literature review then focussed on a systematic search of the literature in relation to experience and COPD, firstly exploring if experience in COPD was being measured and then delving deeper into the understanding of the qualitative literature that surrounds the lived experience of people with COPD, and described in detail the impact it had on daily life from diagnosis to end of life care. This next chapter will explore further areas that have been touched on in previous chapters but now with a clearer focus on the meaning of healthcare measurement through instruments leading to the aim and objectives of this study.

3.2. Patient Satisfaction

Patient satisfaction was discussed in the opening section of the literature review in terms of the misconceptions that surround the terminology of patient satisfaction and that of the measurement of healthcare and the measurement of quality care which is now the focus of healthcare delivery. Much like the descriptors highlighted in Chapter Two Table 2.4 the experience and terminology is varied across the health service, from a series of smiling and angry faces, or tick boxes to describe

your personal satisfaction of a clinic appointment, to the annual NHS patient satisfaction surveys. Patient satisfaction surveys are now routinely used in hospitals in many European countries as a benchmark of how well services are performing from the 'patient perspective' (Säilä, Mattila, Kaila, Aalto, & Kaunonen, 2008). In a range of NHS hospitals and general practices in the UK, it is possible to complete satisfaction surveys at electronic booths in hospital foyers or as you leave the building at GP practices, moving towards real-time patient satisfaction feedback (Southampton University Hospital; Clapham Family Practice). This data is then often used to describe the 'patient experience' in quality accounts or trust reports.

3.2.1. Patient Experience – Measuring what is important

As Chapter One suggested there is a national drive to collect patient experience across NHS services and report for NHS organisations. The Health Foundation (2013) undertook a comprehensive evidence scan which explored further the concept of patient experience in the health service. The Health Foundation report (2013, p.20) like others (Black, 2013; Cornwell, 2012) advocate that the measurement of experience could potentially enhance patients' expectations, experience and satisfaction of healthcare. The evidence scan explored 328 empirical studies and gives a comprehensive overview of the current literature published, but, most importantly, understands and highlights that there are a number of different options for the ways in which healthcare can be measured as shown in Figure 3.1.

Figure 3.1 shows the number of examples of methods used to measure patient and carer experience of health services. Reproduced from Health Foundation Report (2013, p.7).

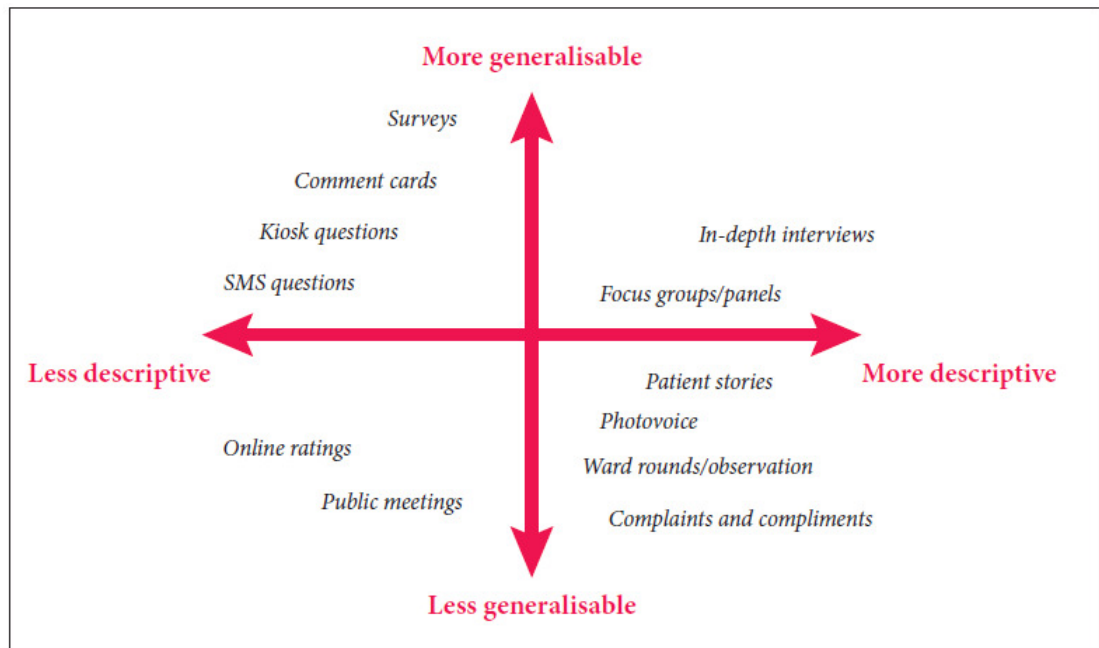


Figure 3.1 Methods of Patient Feedback

Figure 3.1 demonstrates that qualitative methods such as one to one interviews focus groups, which give more descriptive data as evidenced in Lindgren et al., (2014); Powell et al., (2013); and Lowey et al., (2013) previous papers in the studies of experience and living with COPD. There are also less descriptive methods of collecting data, such as using surveys and comments cards as used within. An example of this is the NHS England's Family and Friends test as previously introduced in Chapter One (Dixon-Woods, Minion, McKee, Willars, & Martin, 2014). There remains confusion among health professionals between the definitions of experience and the terminology and the collection of 'patient

experience'. The difference between healthcare professionals' definition of experience vs. satisfaction in these new methods of measurement such as the family and friends test (Hodson & Andrew, 2014) .

It has become clear that the different measurements and the collection of healthcare experience cannot be undertaken simply by one specific measure or measurement, because healthcare remains complex and varied, and there are a number of different elements that potentially impact on the measurement of experience in multifaceted health systems such as the NHS (Beattie, Lauder, Atherton, & Murphy, 2014, pp.1-4). However, it is critical to understand which methods to use to measure so that the right evaluation of the phenomena is made, enabling meaningful data to be collected which support service development or improve quality care (LaVela & Gallan, 2014). Traditionally, however, patient experience measures seek to measure the topics of the most significance to the majority of patients (Graham & Woods, 2013). And an important aspect to note in the development of any new instrument is that they should be based partly upon evidence of what matters to patients, which is clear within the qualitative descriptors of experience and as identified by Disler et al. (2014).

3.2.2. Patient Reported Experience Measures (PREMs)

PREM is a measurement of a patient's perception of their personal experience of the healthcare they have received. PREM instruments should focus on the aspects of the care that matter to the patient (Coulter et al 2009). PREM results can be used to improve services and provide a patient view on these improvements that

moves away from the technological or economic model that is often employed in service design.

In contrast to PROMs, which have been utilised widely for elective surgical procedures, there has been very little research or practical application of PREMs. The Picker Institute UK have come closest with a number of questions within the UK based national NHS patient survey that explores generic patient experiences (Jenkinson, Coulter, & Bruster, 2002) using survey methods. As the previous literature suggests much of what has been collected in COPD has been descriptive data or feedback on symptoms, or experience of intervention used to improve service re-design.

The previous rigorous literature review (Chapter Two) identified that there is, to date, no condition-specific PREM for COPD. While generic PREMs are important, they risk losing elements of a patient's experience that are specific or weighted towards a particular disease or illness that is the dominant reason for a patient seeking healthcare assistance. These issues are even more complex in that a disease-specific healthcare experience for a patient may involve different facets of care that reflect different aspects of a patient pathway or journey, for example, a hospitalisation for a severe exacerbation compared with a routine annual review in primary care. This may be similar in other complex long term conditions. The previous empirical scan (Health Foundation 2013), already highlights further a number of different surveys and questionnaires for measurement of experience in primary and hospital care, as well as the measurement for carers. One example is the Annual General Practice Patient Survey in England (GP-patient, 2014) designed to assess and review patients' experience of general practice. However, a qualitative study of GPs and practice

staff suggest that there is a mismatch between the design of the survey and the actual patient 'satisfaction' reported (Asprey et al., 2013). This highlights and supports the earlier discrepancies around terminology of experience and satisfaction used within this type of service provision reporting on patient experience. Williams, (1994, p.509) agrees, suggesting that many satisfaction surveys only provide a false impression of consumerism, producing results which tend only to 'endorse the status quo'.

Both European international audits in COPD (Roberts, Luis Lopez-Campos, & Hartl, 2012) and UK National audits (Stone et al., 2009) and have shown significant deficiencies in acute hospital care for COPD when benchmarked against the guideline audits, reporting wide variation between acute hospitals. In response these audits the Department of Health have produced a national service strategy document, underpinned by the National Institute of Health and Care Excellence quality standards. This document suggests that the measurement of patient outcome metrics. The suggested metrics measurement of both PROMs and PREMs for COPD gaining new insight with patients with COPD (Hodson et al., 2013, p362). PREMs also have the potential to noticeably change the consultation with patients by re-focusing from what the clinician wishes to discuss to a patient-centred approach with interaction based upon what is important to the patient. In the context of this thesis a disease specific PREM in COPD is essential. The need to focus on patients' experience and capture important episodes in the patients journey such as 'exacerbations' are essential to the positive experience of a patient's understanding of the healthcare system.

At the time of writing, there are no COPD-specific PREMs that can be employed to measure the quality of a patient's interaction with healthcare, and reliance

is currently being placed on generic measures such as the national NHS Survey and GP survey to capture experiences of living with COPD. However, there are steps to explore further the concept of a PREM in COPD as the previous systematic literature showed (Hodson et al. 2014). A 5-year national audit for COPD (Royal College of Physicians 2013) for the first time has explored the feasibility of measuring a PREM in the COPD population by initially exploring a number of different patient collection sources (British Lung Foundation, 2014 in press).

3.2.3. Patient Reported Outcome Measures (PROMs)

PROMs are self-report questionnaires or scales, and seek to measure patients perceptions of their health status or health-related quality of life, normally completed by patients (Hodson et al., 2013). PROMs are familiar research tools and are widely accepted, but are now ever more used to direct individual patients as a measure of an intervention and to provide patient related comparative data across health care providers. And are potentially a useful measure of quality from the healthcare provider or clinician (Black, 2013).

PROMs can be variable in their application to a population or even to a specific condition. The content tends to focus on one or more of physical functioning, symptoms, social wellbeing, psychological wellbeing, cognitive function and role activities such as the St Georges Respiratory Questionnaire (SGRQ) does (Jones, 2011). Patients score their perceived status against a statement with a scale. The European Quality of Life Instrument (EQ-5D) (EuroQol, 1990) is an example of a generic PROM and the Oxford Knee Score (Dawson, Fitzpatrick, Murray, & Carr, 1998) is another example of where a condition specific tool has been

developed. For a PROM to be used in routine clinical practice it must be simple to complete and contain few items concentrating on those relevant to the patient. The EQ-5D has 5 domains with 3 questions in each while the Oxford Knee Score uses 12 questions covering mobility, pain, and activities.

Since 2009, following reports recommending the introduction of PROMs use in the NHS (Darzi, 2008; Darzi., 2007) all NHS hospitals have been required to ask patients to complete a PROM questionnaire before and after four specific elective surgical procedures with results being published nationally. Black, (2013, p.346) stresses that the measurements and benefits of PROMs are still not fully known in the healthcare service. This is because of a combination of reasons partly as PROMs are embedded in research but also that they are commonly not used as in other countries.

While PROMs for long-term medical conditions, such as COPD, as yet, do not appear in this formalised NHS data collection, they may in the future of care. Traditionally, PROMs for elective procedures are usually administered before and after the surgery itself to measure effect. Such an approach may be more difficult for some medical conditions, for example, an exacerbation of COPD, when patients are unwell. However the addition of such measures provides a new knowledge with which we can assess the effectiveness of an intervention. There are a number of COPD specific PROM instruments which are broadly acknowledged forms of measurements in trials, for example the COPD Assessment Tool (Jones et al. 2009), and Chronic Respiratory Disease Questionnaire (CRDQ) (Jones, 2011) both of which are self-reported questionnaires and used widely within current COPD research (Kaplan, 2010). The CAT is a COPD specific PROM designed to focus on the

impact of symptoms on everyday life but is a much easier self-administered questionnaire consisting of 8 items (Jones et al. 2009) compared to the CRDQ of 20 questions.

An example of where PROMs are used widely in COPD care as an outcome of intervention is in the area of pulmonary rehabilitation and research. These programmes consist of an education and exercise and is the commonest intervention to effectively measure PROMs as a measure of patient reported outcome and measure for use pre- and post-intervention, in this case education and physical activity. The Quality standards produced by the BTS (2014) make recommendation that the measurements of simple PROMs are an effective measurement of outcome. Measurement of PROMs in PR has been standard in many clinical trials results in grade A evidence in PR (Mikelsons & Wedzicha, 2009; Murphy et al., 2011; Seymour et al., 2010). An example of this is a multi-centred, prospective study (n=261) using the CAT within a pulmonary rehabilitation setting which demonstrated that the CAT could be used as a simple outcome measure as it improves in response to PR and allows for different categories of response (Dodd et al., 2011).

It is clear that PROMs have become a common outcome measure used in a number of different clinical areas within healthcare. PROMs add a different aspect: they are more patient-centred than the measurement of satisfaction alone. If used correctly they are simple and effective 'measures' of clinical intervention, becoming routine in clinical practice. However, how can the 'experience' of this intervention be captured? Further work needs to be done with the use of disease-specific PREMs and PROMs to determine their possible relationship to further improve the quality of life for patients living with COPD.

3.2.4. Quality of Life

Shortness of breath, dyspnoea, breathlessness are all common descriptors of experience used to describe the most documented symptom experienced by people living with COPD. It is recorded by COPD patients as having major impact and an increased burden on health related quality of life (QoL) (Disler et al., 2014; Giacomini et al., 2012; Lowey et al., 2013). The measurement of quality of life has been reported on for many years. Mandzuk & McMillan, (2005, pp.12-14) claim that the use of the terminology of the concept health-related quality of life (QoL) is however, very often misunderstood or ill defined. This is emphasised more clearly by Allison et al., (1997, pp.221-222) who suggest the underlying construct of QoL instruments are often not valid, concentrating much more on the content rather than the relevance of the measurement and the complex aspect of constructs such as QoL.

Quality of life is also being measured by the vast number of PROMs which were identified earlier as ways in which to interpret the views of patients in everyday activity or through the impact of intervention. This leads to a broader understanding of terminology used to describe quality of life measurement. The themes and descriptors used in the literature review of experience of patients with COPD also has a clear association with quality of life, from impact on symptoms, such as breathlessness and cough, to the effects of COPD has from diagnosis through to end of life care. A number of generic outcome measures explore specific aspects of care. An example of this is the use of the Dyspnoea-12 (Yorke et al, 2010) which was developed to give a global score of breathlessness and encompasses both 'physical' and 'affective' aspect but critically over a

number of different lung diseases such as COPD, Interstitial Lung Disease (ILD) and Heart Failure (HF) (Yorke, Moosavi, Shuldham, & Jones., 2010, p.21).

3.3. Why COPD-Specific measures?

3.3.1. COPD and PROMs

As previously suggested it is evident that measurements that have been developed and validated for use with a specific condition such as COPD for identifying the evidence of views, opinions or experience being sought are far better than the use of more generic non-specialist measures at reflecting the emphasis on the holistic specialist needs of the patients (Hodson & Andrew, 2014; Weldam, Schuurmans, Liu, & Lammers, 2013). It is now common practice that COPD health measurement or quality of life measurement are central to research and that reported changes in these have become a major driver for presentation and quantifying research affect (Jones, 2001).

PROMs are now a regular aspect of measurement of outcome not just in pharmacological research, but also in interventional studies in COPD. One such example, is Davey et al., (2014) who used a number of PROMs as 'outcomes' in the use of lung volume reduction surgery with endobronchial valves, in patients with heterogeneous emphysema. Davey et al., (2014, p.2) identified a number of PROMs such as the 6 minute walking test (6MWT) and other outcome measures such as the CAT and quality of life measurement questionnaires (EQ-5D). These together were used to monitor secondary endpoints to the study, using changes in FEV₁ as the primary outcome.

3.3.2. Assessment of COPD

Terminology used in the assessment and measurement in COPD is confusing as to what is an 'outcome measure' of patient experience, satisfaction or of outcome intervention. There are an excessive number of patient reported instruments either disease specific or generic. Current instruments used widely in COPD constitute testing or assessing COPD through symptoms or endurance. The assessment in COPD merely becomes tailored on 'descriptions' of 'symptoms' and impact as outcomes for the overarching aim of improving COPD care for patients. Pulmonary Rehabilitation is a good example of where assessment of patient reported outcome, satisfaction and the experience of patients can be combined. This develops an 'overarching holistic assessment' of patients and 'outcome' based upon their experience, that is individualised and maximising patient-centred care and improving the quality of care measured by effectiveness of the service (PROM indicators) plus the patient experience. Further evidence is needed to understand fully the holistic understand of PREMs and PROMs together in providing and measuring holistic care for COPD patients.

Like patient reported outcomes or (PROMs), terminology remains fragmented. Partly this has come from the vast number of instruments that have been developed which are either condition specific (CAT or SGRQ) or more generic but mapped within the respiratory umbrella. Validation and reliability in instrument development should remain at the heart of this alongside the patients and should remain the key factors in choosing an instrument to use with patients. But what is most important in all of this, and the key question, is what is being measured, and why? The early concepts of quality and patient experience are a third component of this suggestion that alongside the measurement of a patient reported outcome

you need further engagement with PROMs, PREMs and a measure of health status measures to compliment the vast number of measurements of instruments on patients. This is supported by previous work by Cornwell (2012, p.1) who recommends that patient experience should be aligned with other measures such as PROMs and health-related QoL measures such as the EQ-5D (Dolan 1997). There is currently a National Royal College of Physicians COPD audit reviewing three aspects of COPD care: primary care, pulmonary rehabilitation and secondary care. Alongside this there is a national recognition that the patient experience should also be captured alongside the medical, operational and clinical aspects of the COPD audit. A recent feasibility study by the British Lung Foundation (2014) explored a number of different options for the collection of patient experience data through on-line, postal and 'live' patient data collection. Preliminary results are indicating that postal questionnaires give a much greater return rate than relying on healthcare professionals or patients completing questionnaires on line (Picker Institute 2014). These different perspectives in patient data collection need to be considered to ensure that the data collected is meaningful, patient centred and that healthcare can develop and learn from this data to ensure quality care both now and into the future.

3.4. Questionnaire Design & Validation

The need to ensure that questionnaires or surveys have a robust methodology and appropriate methods used including sample size and population to reduce bias and appropriate rigor with a structured validation process through the testing of the proposed questionnaire through reliability and validity is important. The benefits of questionnaires include quick and reliable data to enable the appropriate analysis

and data collection (Rattray & Jones, 2007). The use of questionnaire design will be discussed further in Chapter Four.

3.5. COPD PREM Development

This following section will outline the overarching aims and objectives of the development of the patient experience measure in COPD as introduced within the introduction chapter of this thesis know as Study Two.

3.5.1. Aim of Study Two

The overall aim of this thesis (Study Two) was to continue the previous work of Study One (COPD PREM development) by developing a reliable and validated disease-specific patient reported experience measure (PREM) in COPD. The concept of the development was for the COPD-PREM to be used in everyday clinical practice by a variety of healthcare professionals from the multidisciplinary team. The COPD-PREM would also be used in a number of clinical settings such as pulmonary rehabilitation, nurse-led clinics or GP COPD annual reviews to support healthcare professionals understand the positive and negative experiences of people living with COPD.

3.5.2. Research Objectives

The following five research objectives were identified as part of this study:

- **Objective 1:** To develop a COPD PREM item list that is relevant across all severities of COPD (Study One);
- **Objective 2:** To refine and reduce the preliminary list of items to fit a psychometric model through Rasch analysis;
- **Objective 3:** To assess the reliability of the final COPD PREM items;

- **Objective 4:** To assess the validity of the final COPD PREM items;
- **Objective 5:** To assess whether the construct validity of items varies by patients clinical and/or demographic characteristics.

The development of the COPD-PREM overarching aim is to improve the quality of life and care provided to people living with COPD. Through clinical audit, benchmarking and improving services for COPD patients. Whilst, engaging in conversation with patients using the PREM instrument to guide and improve the current experience of COPD patients. Overall thereby improving the accountability, transparency and quality of care provided to patients living with COPD.

3.6. Conclusion

There is a vast sum of literature summarised within these three main papers and reports: The Health Foundation (2013); LaVela & Gallan., (2014); Beattie et al., (2014) relating to the complexities and different constructs of healthcare measurement. Healthcare professionals' views on the understanding of measurement and definitions of patient satisfaction, experience and outcomes for patients is varied. However, what is evident is that conflicting terminology, not only just in what is written in the literature but also on the focus on the national definitions is also misunderstood.

The current challenge needs to focus on the robust holistic assessment of patients, using the most appropriate tools in patient' measurement. The need to support healthcare professional assess and meet these needs of patients while designing quality services to ensure patient-centred care to measure quality and patient experience needs to be undertaken through a wider concept of both the collection of qualitative and quantitative data.

The development of a disease specific patient reported experience measure (PREM) instrument in COPD, will add to this diverse number of measures, but through its robust design methodology and development. There is a need to measure the vast descriptors identified in Chapter Two which will help support the measurement of experience rather than the continued reporting of living with experience, to make a difference or change in health care.

CHAPTER FOUR

CHAPTER FOUR

4. Development of a Patient Reported Experience Measure in COPD

4.1. Introduction

Previous chapters have highlighted the complexities of the measurement of patient experience. And as the Literature Review highlights there is currently no measurement of experience of living with COPD or with the utilisation of healthcare. The results of Study One (COPD PREM development) of the PREM development process supports the current study's aim that descriptions of experience of living with COPD can be quantified using a questionnaire format. The Literature Review did not highlight a measurement of patient experience in COPD; it did, however, support the item descriptors and themes of experience in COPD identified within Study One (COPD PREM development).

This chapter presents the theory underpinning instrument development including measurement theory and key psychometric principles. The application of these principles in this thesis are described in Chapter Five which illustrate the methods used in Study Two.

4.2. Methodology

4.2.1. Latent Constructs and Measurement Theory

Over recent years the development and construction of new instruments by nurses have evolved (Cappelleri et al., 2000; Green & Frantom., 2002; Yorke et al., 2014). The use of these instruments to measure different aspects of health care such as

patient satisfaction, quality of life, and disability/activity, continue to be used in both clinical and research settings. As such, it is imperative that such instruments are developed using rigorous and well-established methods and demonstrate appropriate reliability and validity. Instruments often measure subjective phenomena relating to something we observe in the real world such as a person's perception of their quality of life, symptom experience or satisfaction with health care provision. They also measure phenomena that only exists as part of a theory, often called latent traits, such as an attitude or an ability, which can be measured directly or through observation (Hojtink, 1991). Therefore, experience is a latent trait construct. Garger, ('latent construct' 2014), suggests to measure a latent construct, researchers should capture indicators that represent the underlying construct. In this study, experience, due to the complexities and its varied meaning, is difficult to measure directly through observation.

Previous measurement models of experience have focused on the development indicators and/or measures that are directly reported through self-reported measures such as PREM questionnaires (Jenkinson et al., 2002). A number of generic experience instruments have been developed to capture the experience of patients in relation to different aspects of healthcare and disease specific experience (Health Foundation 2013).

An approach on the design and validation on PROMs by Atkinson & Lennox, (2006, p.65) the claim that the concept of 'self-reporting', suggests that such measurements who use this approach are 'one step' removed from the underlying construct of the PROM, to that of the actual phenomena. Therefore, it is feasible that you may only record what the outcome is measuring and not the observed construct. Because of the inferred nature of self-reported measures,

the development of any new experience instrument needs to ensure that it is credible through appropriate reliability and validity that must be demonstrated by testing the instrument's theoretical relationships to other established criteria (McIntosh-Scott, Mason, Mason-Whitehead, & Coyle, 2014). There are several methodological approaches to consider in the measurement of experience.

4.2.2. Levels of Measurement

A level of measurement refers to that of a relationship between the numerical values assigned to the attributes that underpin a variable. In other terms, there can be many ways to measure a certain aspect of the underlying construct. For example, height can be measured in feet or inches, but it can also be classified as short, tall or very tall. The results are critical to understanding the statistical tests that can be undertaken on the results that follow. There are four main levels of measurement, these being nominal, ordinal, interval and ratio.

Nominal is typically used for classification for example male or female, a.m. or p.m., and a number is then assigned to the word: male=1 and female=2, for instance. Nominal data can be used to categorise the data collected. This type of measurement will be used when results of some of the demographic data will be entered into the statistics package for analysing results.

Ordinal measurement enables the researcher to collect data that provides a direction, for example low medium high or hot or cold. There are a number of additional outcome measures for breathlessness, for example, that provide a level of ordinal data. For example, participants could be ranked by the intensity of breathlessness, frequency of occurrence or its effect on activity or quality of life. For daily activity limitation, the scale could be 0=no limitation; 1=some limitation;

2=moderate limitation; and 3=severely limited (Yorke et al., 2010). The Medical Research Council scale (Appendix Seven) is also a good example of the collection of ordinal data and is a tool used in Study Two.

The final two levels of measurement are interval scales, which take the idea of ranking items in order one step further, since the distance between adjacent points on the scale are equal. A good example of this is the measurement of time on a 24-hour clock. For example, it is the same difference in time if measured between 12:00 and 13:00 compared to 12:00 and 01:00. Other example of measurements in intervals is the measure of temperature. Temperature can also be used in the final scale of measurement 'ratio'. Ratio data is a special kind of interval data. Like interval data, ratio data is measured on a scale that has equal gaps or intervals between the points on the scale. However, with interval data the zero-value on the scale has no *numerical* significance attached to it. It is merely a convenient but not an essential point on the scale. Using temperature as an example, 0°C conveniently describes the point at which water freezes. However there is no reason why this point could not be assigned another numerical value (as it is using the Fahrenheit scale). On an interval scale, the zero-value does not signify a necessary end-point to the scale. It is possible to measure temperatures of -10°C , -20°C and below.

Another example of a ratio scale often used in research is *time*. In this sense it would be impossible for a participant in a reaction time experiment to obtain a score of less than 0 seconds. The participant would only obtain a score of 0 seconds if his or her response were instantaneous.

4.2.3. Constructing Measures

The development of new instruments can be intricate and requires a number of different steps to ensure that the instrument developed is reliable and valid for use. The diversity in the types of measurement models exist in the psychometric testing of instruments to ensure the quality of the instrument and to develop and demonstrate its reliability and validity (Polit & Beck, 2012). For the purposes of this chapter the underlying construct of measurement will focus on two main psychometric theories: Classical Test Theory (CTT) and Item Response Theory (IRT). Much of the earlier work surrounding psychometric testing and the reduction of items within an instrument was guided through the CTT (Nunnally & Bernstein, 1994, p.65). Contemporary psychometric approaches one being Rasch, apply IRT for the development and refinement of instruments (Pallant & Tennant, 2007, p.7). Rasch analysis is the most commonly applied approach in health care and is recommended by the US Food and Drug Administration (FDA) (Appendix Twelve) for the development of patient reported outcome measures (U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research, U.S. Department of Health and Human Services FDA Center for Biologics Evaluation and Research, & U.S. Department of Health and Human Services FDA Center for Devices and Radiological Health, 2006). Through the development and methods of item reduction, contemporary models have become more accepted, in particular Rasch analysis, which has grown momentum not just in developing new instruments (Green & Frantom., 2002; Tor., 2011; Yorke, Horton, & Jones, 2012A) but also in the assessment of well-established instruments (for example the Hospital Anxiety and Depression scale) (Zigmond and Snaith, 1983) in order to gain a greater understanding of their measurement properties (Pallant and

Tennant, 2007). These two psychometric approaches are concerned primarily with the same challenge, measuring a subjective phenomenon (a single point of view), but constructed upon altered levels of mathematical theory and different methods. The next few paragraphs will review these two approaches, CTT and IRT, with the focus being on the theory and application of Rasch analysis.

4.2.4. Classical Test Theory (CTT)

Classical Test Theory (CTT) includes a set of concepts and methods that give a basis for a number of the measurement instruments currently used in health today. These concepts of CTT date back to work by Francis Edgeworth (late 19th century) and Spearman (early 20th century). Central to the theory are three areas, that of the observed score variable is based upon two other components: the true score variable and the error score variable. The principle is that an observed total score on an instrument, X , consists of the sum of a 'true score', T , and an 'error component', E as shown in Figure 4.1:

$$(X) O_{\text{bserved}} = T_{\text{rue}} + E_{\text{error}}$$

Figure 4.1 Classical Test Theory Equation (Millsap & Alberto 2009)

This equation therefore suggests that the CTT for answers to an instrument will only expose a participant's observed score, but this may not always be reflective of their 'true' score. Therefore this equation is highlighting that there is always something in the 'environment' that impacts an individual's performance shown in the equation as a 'error'. It has therefore been suggested that a limitation of the CTT is that any instrument that is designed to 'measure a construct' true score

is limited or flawed due to the possible underlying nature of 'error' in an instrument (Graduates-First, 2014).

One of the founding principles of CTT within psychometric testing is the concept to recognise and develop reliability of psychological tests and assessments. Normally this is measured by the performance of a participant undertaking the test and the difficulty of the questions within a test. Reliability, therefore, is calculated by the participant's individual score on the instrument or test (observed score) and the number of errors in the test itself (error). These two areas give a suggestion of a participant's 'true score', without errors in the measurement. However, as mentioned, random errors can happen due to a number of different reasons such as being tired or hungry as well as errors with the process of testing itself. If a 'common error' however is found this can potentially be removed thereby reducing the 'common error'. A higher test error would generate more positive and reliable scores.

Though a popular theory and widely used for measurement of instruments, to date there have been a number of limitations that have been identified. These include the need for a precisely ordered continuum of items with the purpose of representing a unidimensional construct, and secondly the under representation of additive of rating scale data (Prieto, Alonso, & Lamarca, 2003).

4.2.5. Rasch Model

In contrast to the CTT, the Rasch model is an item response theory which explores how well each item fits to the overall instrument – that is, that all items fit the Rasch unidimensional model and measure the same underlying construct. George Rasch (1960), a Danish mathematician, initially developed a dichotomous

logistic response model that was further developed to include polytomous response options. The Rasch model takes responses for each item entered on a 'linear probabilistic interaction' in terms of a participant's 'ability' and on items of 'difficulty' (Rasch 1993). The Rasch model creates a line of measurement with the items located hierarchically and presents a group of fit statistics. Fit statistics in Rasch show just how well the different items entered in the instrument describe the group of participants and how well individual participants fit to the total group (Prieto et al., 2003). Wilson, (2005, p.123) clarifies that 'fit statistics pinpoint problem items and can be helpful in diagnosing the causes of problems'. Essentially, the model examines the relationship between the latent traits and their response to the items tested in a proposed instrument. Therefore in the measurement of experience in COPD, patients' responses in the Rasch model will make an association between the level of item experience (0=good and 5=bad) experience compared to the underlying latent variable being measured by the instrument (individual item patient experience).

The Rasch model deals with scales that have a multiple response, allowing for the results of these to be summed together and then tested against what is expected by the model. This turns out to be a probabilistic form of Guttman scaling (Tennant & Conaghan, 2007). Thus, if an item associated with a good experience is confirmed by a participant, there is a high probability that other items with a lower score will also be confirmed by the same participant (in this thesis participants who have good experience are more likely to score lower on all items). The probability of a participant choosing a definite response to an item is called the log-odds (i.e. a logistic function) of the difference between the level of experience represented by the item and that possessed by the participant. The experience estimates are

probabilistic and reported in 'logits' – the log-odds of affirming an item (Tennant and Conaghan, 2007).

Therefore the Rasch model is designed to be a template in what the model expects and the actual data being read. There are also a number of other concepts which are taken into account such as category ordering (do the categories of an item work as you would expect them to?). It also explores item bias.

Using the Rasch model and entering the raw data into this model enables a well-designed approach to undertaking a number of key methodological approaches associated with scale instrument development and construct validation needed for the PREM-COPD development. The Rasch model has already been used to develop a number of patient reported outcomes commonly used in COPD care (Yorke et al., 2010; Jones et al., 2009), thereby already measuring different constructs of COPD care such as symptoms and health status. Rasch has also been used to test a number of different instrument developments in long term conditions and experience measurement such as Parkinson's, Multiple Sclerosis and Stroke care (Franchignoni, Giordano, & Ferriero, 2008; Mills et al., 2012; Mills, Young, Pallant, & Tennant, 2010).

The Rasch model is being used as the underlying theory base for the development of the preliminary COPD PREM. This model allows instruments to be designed with a set of items which are intended to be summed together to provide a total score. This model has been designed to meet expectations and demonstrate unidimensionality. This approach enables the model to measure one attribute at a time, allowing for items to function in unison to form a single underlying pattern

in a data matrix (McNamara, 1996). In Rasch terms, this means that all of the non-random variance created within the data can be accounted for by a distinct single dimension of difficulty and ability (Sick, 2010).

CTT and IRT are, in general, consistent and balanced; however, the Rasch model makes more rigorous assumptions and has several advantages over the CTT. For example, the Rasch model broadens the conception of reliability. With CTT, the accuracy of an instrument (i.e. the degree to which measurement is free of error) is marked on just a single estimate of reliability – which is the ratio of true score and observed score variance (Borsboom, 2005, pp.6-8). This is restricted to providing a test's average reliability. Therefore, the measurement accuracy at particular score levels is unknown, whereas in the Rasch model the analysis measures scale accuracy across the instrument's entire scaling range, even though it may not be consistent across the whole range. Rasch analysis tests the functioning of each item at different groups of severity levels (referred to as class intervals) (Tennant and Conaghan, 2007). Rasch analysis enables the severity score for both the participants and the severity of the questionnaire items' responses to be located on the identical metric scale (Tennant and Conaghan, 2007). This means the participant and severity of an item can be evaluated significantly.

4.3. Key Concepts in Measurement

4.3.1. Instrument Characteristics

The development of an instrument is a complex science and instruments can possess many different characteristics, each requiring assessment to ensure that it captures and measures what it purports to be in a reliable and valid manner.

Chapter Three gave a broad overview in the different types of current measurements used within healthcare including the use of PROMs, patient satisfaction and experience measures.

4.3.2. Instrument Response Options

There are a number of diverse instrument designs and response or item scaling options that can be used to measure the phenomenon of interest. The response options used will be different depending on the theoretical underpinnings and aims of the instrument being constructed. This also clearly impacts on future analysis decisions.

The Likert-type scale, sometimes known as a frequency scale, is the most common scale used within outcome measures for COPD care (Jones et al. 2009). This type of scale is fixed choice so aims to discover a participant's particular opinion or attitude. It collects ordinal data on, for example, how strongly a person agrees or disagrees with a statement or the severity of a symptom, for example. The advantage of this type of scale allows for a degree of opinion and enables for a wider breadth of understanding for further research and comparison. However, one of the major disadvantages of this type of scale is that it allows the participant to have some variance in their response and they may therefore rate a symptom more positively than a true reflection would see (McLeod, 2008). This type of scale, along with dichotomous scales, can be divided into categories. Normally a yes/no questions are used, but it can also include other types of categories such as true/false or agree/disagree. Each dichotomous scale must have only have one answer and cannot be both. An advantage of this type of scaling is that it gives a clear and concise answer, therefore reducing bias. However, disadvantages of

this type of scaling are that it limits the responses to a question, and, therefore, the data is not as rich given the simple data to be analysed. Many phenomena measured in health are not as simple as being present or not; rather, they exist along a continuum of frequency of occurrence or severity. This is familiar in the instrument design for patient satisfaction surveys. The GP Patient Survey (Picker 2013b) was a clear example of a design using of both types of scales in one instrument.

A further example of instrument response items at interval level is a semantic differential scale. This is normally a seven-point bipolar rating scale using adjectival opposites, and it was developed by Osgood, Suci and Tannenbaum in the 1950s. An example of this could be the rating of happiness on a scale of 1 to 7, with 1 being happy, and 7 being unhappy. The participant chooses a number from 1 to 7 to answer that particular question. An advantage of this type of scaling is that it is easy to implement, but also gives the participant a range to choose from. A disadvantage, however, like the Likert scale, is that these types of options leave open the door to wide variance.

4.4. Instrument reliability and validity

4.4.1. Internal Reliability

The reliability of an instrument is important in demonstrating that the values assigned are consistent and that it can be used repeatedly, (Rattray & Jones, 2007). This section will highlight a number of the statistical measures that test these qualities and form part of the overall Rasch model analysis too. In any instrument development, one of the first phases is to undertake an hierarchical item reduction, which enables items that have been tested in a population to

assess for any correlations with a number of different population characteristics such as age or gender to be removed, thereby ensuring the development of the reliability of the instrument to ensure satisfactory properties (discussed further in the methods in Chapter Five).

A common practice in developing new instruments is to demonstrate the reliability of the instrument by displaying the use of the Cronbach's alpha (α) statistic. This statistic uses inter-item correlations to decide whether constituent items are measuring the same construct (Jack & Clarke, 1998; Rattray & Jones, 2007). There are a number of different levels of alpha measurement depending on what is being measured, but for comparing groups, α values of 0.7 to 0.8 are regarded as satisfactory. For clinical purposes, reliability of α values should be higher with the minimum being 0.9 (Bland & Altman, 1997, p.572). Specifically to the Rasch analysis the analogous measure is the Person Separation Index (PSI). The PSI is equivalent to the α statistics, and Tennant & Conaghan, (2007, p.1361) recommend that the minimum value of 0.85 is appropriate for individual use. The PSI is the estimate of logit scale for each person and formulates part of the overall fit statistics shown in the Rasch model.

To ensure stability of an instrument over time, it is key that the instrument being tested is reviewed and is able to track and is sensitive to change over time. A test-retest method of reliability can be an effective measure of stability over time and can be used to review its consistency over time (Frank-Stromborg, 1988). Any new instrument development needs to ensure that for its reliability the results of two measurement points offer no significant changes in the two points measured. This is an important factor if instruments are to be used in clinical audit or for use

in patient assessment as an instrument to detect patient change (Rattray & Jones, 2007).

4.4.2. Internal Validity

An essential element to instrument development is its validity. Validity is fundamental to ensuring that the instrument measures what it is supposed to (Rattray & Jones, 2007, p.236). Validity can be complicated to establish. A simple initial approach is whether on face value the questionnaire appears to be measuring what it was set out to do. Face validity is a simple way to either get expert opinion or patient involvement in the questionnaire construct and whether at face value the questionnaire covers the construct that is potentially being measured (Nevo, 1985). This however, is not adequate enough to ensure a robust validity to any instrument development and a process called 'construct validity' is another key element to the Rasch process. This process involves correlating the new instruments with existing validated instruments that relate or are used widely within the measured areas. Thus it is important that data is also collated as part of any instrument development and study design. Correlations against these different measures can then be made and subsequent validity sought or acknowledged.

4.5. Summary

This chapter has explored the underlying methodological approaches to instrument development focusing on key aspects and starting to introduce some of the main psychometric principles such as the classical test theory and item response theories. It is acknowledged that there are a number of other item response theory's that could have potentially been used within this study.

However, the Rasch model was a familiar model used within COPD and healthcare, there was also additional support and expertise in the Rasch model and not others. In summary, Study Two will adopt a test-retest questionnaire development design. The analytical approaches using the Rasch model are designed to identify the appropriate items to develop a preliminary COPD-PREM with items that have the most reliable measurement properties, and are free from bias in relation to age and gender, and fit a unidimensional model in Rasch. The reliability and validity of the proposed new instrument will be tested using the PSI and fit statistics as demonstrated in the Rasch model.

Further detail on the specific methods used in Rasch and how this will be applied to the development of Study Two will be shown further in Chapter Five.

CHAPTER FIVE

CHAPTER FIVE

5. Outline of Study Plan

5.1. Introduction

The research plan outlines the development of a new instrument to measure the experience of patients living with COPD. The two studies as previously mentioned will be explained further and divided into four phases. The two studies are known as Study One (Andrew et al., 2012) which is applied to the instrument's development, and Study Two, the testing, refinement and subsequent reliability and validity testing. Both studies involved a number of different steps and different patient populations. My role part of the leadership team for Study One. This role included research design, ethics, recruitment of participants, undertaking interviews and analysis of results. In Study Two (this thesis), the author undertook and led the development, conduct and analysis of the study. Study Two is the main focus of this thesis and sets out to reduce the item set further through a hierarchical item reduction and Rasch analysis, generating a newly developed instrument, while testing its reliability and validity.

5.1.1. Overarching Study Plan

STUDY ONE (completed)

1. Identification of items for initial inclusion using discovery interviews with patients with COPD;

2. Development of the initial selection of a 38 item pool through thematic analysis of interviews.

STUDY TWO

Phase I: Item reduction

1. Hierarchical item reduction
2. Further item reduction using Rasch analysis

Phase II: Preliminary reliability testing and structure of the final item set

1. Fit to the Rasch model
2. Demonstrate reliability using the Person Specification Index (PSI)
3. Test and re-test reliability

Phase III: Preliminary validity testing of the final item set

1. Face validity with expert and patient opinion
2. Concurrent validity with clinical variables
3. Correlations with the following PROMs: COPD Assessment Tool (CAT) and Hospital Anxiety and Depression Scale (HAD).

5.2. Background Overview of Study One

5.2.1. Study One – Development of the initial selection of 38 item pool

The initial instrument development (Study One) and funding of the initial phase was commissioned as part of the North East London, North Central London and Essex, Health Innovation and Education Cluster (NECLES HIEC), in partnership with Anglia Ruskin University. The research team for Study One and Two was multi-disciplinary, including nurses, academics and professors of nursing and

professors of respiratory medicine. The author, a COPD nurse consultant, was project team lead throughout Study Two and was responsible for the development, conduct, analysis and reporting of the work.

The Study One research was not conducted as part of this doctorate submission but the author led on its development and was also involved in the recruitment, interviews and wider development of the item pool. For clarity and context however, for this chapter an overview of the findings are highlighted and the full report found (Andrews, et al., 2012) in Appendix One, as it formulated the basis for Study Two as the findings from Study One (COPD PREM development) led to the items generated for the next phase of the instrument generation and creation of the final instrument.

A small team from the HIEC set out to develop a COPD-PREM in partnership with the British Lung Foundation and Royal College of Physicians. Following the development of a protocol and ethical approval the experiences of living with COPD for 64 patients with COPD across the community of North East London, North Central London and Essex (NECLES) region, with a range of COPD severity and presentation. A further 19 patients with recent (within the last 3 months) hospitalisation due to COPD-related conditions, were captured using a discovery interview technique. The experiences for both groups (n=83) were then grouped and coded separately leading to the development of experience items pertaining to both primary (community) care and acute patient groups. This led to the development of a 55-itemed preliminary experience instrument which was scaled from 0-5 with a good experience item scaled to a poor experience item.

The preliminary instrument Table 5.1 went through an initial face-to-face validity phase with an expert group consisting of a respiratory professor, professor of nursing and the research group (Appendix Three). From this expert panel, each item was examined and discussed and the group reduced the number of items from 55 to 52. Three items were removed as it was professionally felt that they were duplicate items as they asked the same question but in a different sentence construct. Finally, a cognitive debriefing on the remaining 52 items took place through a face-to-face discussion with COPD patients (n=25) (varying severities from mild to very severe) in a number of different places in both primary and secondary care. This included pulmonary rehabilitation groups and one local Breathe Easy group, in East London. It also included COPD patients (n=5) who were under the care of the local COPD 'hospital at home service', and who were all receiving treatments for exacerbations of COPD, and patients who were on the local respiratory ward for exacerbations of COPD requiring hospital admission. This ensured that the instrument items had a degree of patient involvement prior to the large-scale testing. Anecdotal comments included that they could 'relate to the instrument' as it used 'words' that described their COPD such as 'scared' and 'frustrated'. No changes were made to the instrument post the face-to-face discussions with patients. Therefore the 53-item PREM (Table 5.1) was submitted as part of the Study Two PREM COPD in two phases: one, concentrating on 38 items in four domains of long-term primary (community) COPD care:

1. My history with COPD;
2. Usual care in COPD;
3. My everyday life with COPD;
4. COPD exacerbations.

And a further 14 items concentrating on hospital experience were split into 4 domains as follows:

1. On arrival at hospital;
2. On the ward;
3. Discharge from hospital;
4. Follow-up care.

The Hospital preliminary COPD PREM instrument development is being undertaken in a separate study and does not formulate part of this doctorate.

Table 5.1
Phase one: Preliminary COPD PREM-38 Item instrument.

MY HISTORY WITH COPD								
These questions are about your health history with COPD								
No.	Low Score	0	1	2	3	4	5	High score
1	I am not shocked by my COPD diagnosis							I am shocked by my COPD diagnosis
2	I have come to terms with my diagnosis of COPD							I have not come to terms with my diagnosis of COPD
3	I have given up smoking and I am confident that I will not start again							I have given up smoking but worry that I might start again
4	I want to stop smoking and I believe I can							I want to stop smoking but I believe I just can't
5	It was a relief to have a diagnosis for my symptoms							Not having a diagnosis for my symptoms was frightening
USUAL CARE IN COPD								
These questions relate to the everyday usual care given for your COPD								
	Low Score	0	1	2	3	4	5	High score
6	I understand my diagnosis							I am confused about my diagnosis
7	I am confident that my GP will listen to my point of view							I am concerned that my GP won't listen to my point of view
8	I am very pleased with health care workers who look after my COPD that I see on a regular basis							I am not at all pleased with health care workers who look after my COPD that I see on a regular basis

9	I am happy with the length of time that it takes to get an appointment with my GP when I need to	I am angry about the length of time that it takes to get an appointment with my GP when I need to
10	I really enjoyed pulmonary rehabilitation	I didn't enjoy pulmonary rehabilitation
11	I found pulmonary rehabilitation useful	I didn't find pulmonary rehabilitation useful
12	I understand my condition and this helps me to manage my fear	My lack of understanding about my condition makes me frightened
13	The information I have been given from the health care workers about my COPD is consistent	I have been given conflicting information from health care workers about my COPD
14	I have enough information about my condition	I am frustrated by my lack of information about my condition
15	I understand about my COPD tablets	I am confused about my COPD tablets
16	I am confused about how to use my COPD inhalers	I understand how to use my COPD inhalers
17	I understand how my COPD treatments work	I am confused about how my COPD treatments work
18	I don't find going to a hospital outpatient clinic frustrating	Going to a hospital outpatient clinic is frustrating
19	I know how to use my inhaler properly	I am confused about how to use my inhaler properly

MY EVERYDAY LIFE WITH COPD	
These questions relate to your everyday life with COPD	
Low Score	0 1 2 3 4 5 High score
20 I have accepted the limitations to my lifestyle caused by COPD	I am frustrated and unhappy by the limitations to my lifestyle caused by COPD
21 I feel that I have good support from others like my family, friends, neighbours or carers	I feel that I don't have any support from others like friends, family, neighbours or carers
22 Overall I am satisfied with my life	Overall I am very dissatisfied with my life
23 I am not depressed	I am feeling depressed
24 Overall I am satisfied with	Overall I am very

	the care given to me	dissatisfied with the care given to me
25	I am not embarrassed to tell others about my condition	I am embarrassed to tell others about my condition
26	I feel that I am in control of my condition	I feel that I don't have any control over my condition
27	I am motivated to keep going and to not give up	I am not motivated and I feel like giving up
28	I am happy to talk about the future	Talking about the future makes me feel depressed
29	I am not concerned about the future	I am concerned about the future
30	I am not worried about the season	I worry about the season and my COPD
31	I keep going and try to enjoy my life	I feel like giving up and I don't enjoy my life

COPD EXACERBATION (Flare up) These questions relate to a flare-up of your COPD		
Low Score	0 1 2 3 4 5	High score
32	I am confident in a 'flare up' I have quick access to treatment e.g. a rescue pack or access to my GP	I am worried that in a 'flare up' I don't have quick access to treatment e.g. a rescue pack or access to my GP
33	I do not feel anxious about my current health	I feel anxious about my current health
34	I am not worried about the care I will get from health professionals when I get a 'flare-up'	I worry about the care I will get from health professionals when I get a 'flare-up'
35	I am not scared of getting a cold or an infection	I am scared of getting a cold or infection
36	I am not frightened of being breathless when I have a 'flare-up'	I am frightened of being breathless when I have a 'flare-up'
37	I am not frightened to go to sleep when I am having a 'flare up' of my COPD	I am frightened to go to sleep when I am having a 'flare up' of my COPD
38	I try not to panic when I have a 'flare up' as it will make my breathlessness worse	I panic when I am having a 'flare up' and this makes my breathlessness worse

5.3. Study Two: Method and Design

5.3.1. Introduction

The method section on measurement theory (Section 4.2) highlighted the different aspects of instrument development. These tests identify the items with optimal measurement properties. This includes testing items for potential bias (such as gender and age), reliability and validity. Item reduction also decreases patient burden by removing redundant items. This following section relates to the methods used and describes how objectives one and two (p.103) were achieved. However, achieving Study Two involved administering the 38-item instrument to patients with COPD, along with collecting patient demographics and spirometry (FEV1% recorded). Initially, the criteria for the selection of participants and the data collection methods are described in this chapter, along with the methods and process for item reduction to formulate a shorter COPD PREM instrument.

This study adopts a test-retest questionnaire development design. In summary, data was collected by asking participants to complete questionnaires at two time points: time of recruitment (baseline) and one week later (follow-up). This time period is thought to be long enough for participants to recall their experience and for their clinical condition to remain fairly constant. A self-report global health score was also obtained to determine if a patient's perceived general health condition had changed between the two time points. Demographic data was also collected at the time of recruitment using specific data sheets (Appendix Four).

5.3.2. Population and participant recruitment

Participants with COPD were recruited from a number of NHS secondary and integrated care organisations which included pulmonary rehabilitation, respiratory clinics and wards. Also British Lung Foundation Breathe Easy groups (self-supported groups for people affected by lung disease) from various locations across England and the Channel Islands. A detailed process of the recruitment sites and venues is detailed in Figure 5.1.

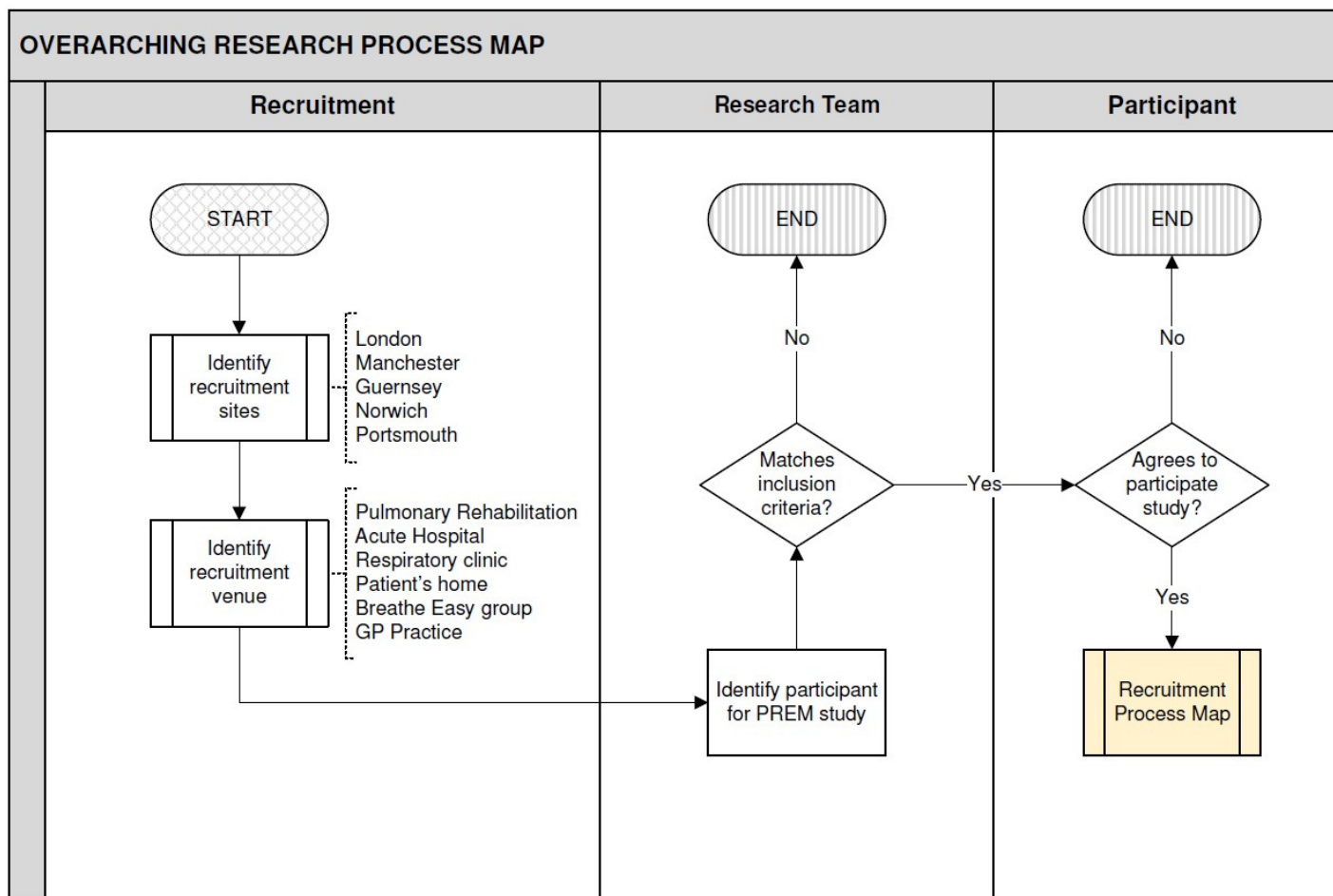


Figure 5.1 Overarching research process map for study two

5.3.3. Inclusion and exclusion criteria

Inclusion and exclusion criteria were developed to ensure that participants recruited from within each recruitment area were consistent. Criteria for inclusion:

- A confirmed diagnosis of COPD (mild to very severe COPD ($FEV_1 < 100\%$ with symptoms));
- Able to consent and sign a consent form;
- Able to follow written and verbal instructions in English (Due to the availability of advocacy services, those whose first language is not English and who are unable to read or understand verbal English will not be able to participate in the study, unless a family member is available to support and translate during the study period);
- Agreed to take part in the study.

Exclusion criteria:

- Other respiratory conditions such as Asthma/pulmonary fibrosis;
- Who are nearing end of life;
- Had significant other co-morbidities such as severe heart failure.

It was important to ensure that a range of patients was recruited for this study to guarantee a fair representation of patients living with COPD across the country with ranging severities. No potential patient was excluded because of age, ethnic origin, disability or gender, however, all patients needed to fulfil the inclusion criteria set and complete the relevant paperwork and understand the consent process.

5.3.4. Recruitment of Participants

A predicted sample size of over 150 was needed to fulfil the aim of the study and the requirements of the Rasch Model. This is based upon a sample size ensuring accuracy for a test-re-test reliability, thereby ensuring that there are at least three class intervals of approximately 50 participants in each class (Pallant & Tennant, 2007). Potential participants were approached by the 'research team' who consisted of nurses and physiotherapists working in respiratory teams. It was also important to ensure that participants were recruited from across different healthcare settings such as pulmonary rehabilitation, outpatient clinics and hospitals.

Potential participants who engaged in discussion on the study were given a patient information sheet (Appendix Five), if the participant showed interest or wished to think about the study further. The research team were available to answer any questions at the time and afterwards. All participants, of course, had the right to decline to take part in the study, from the initial discussion and at any time and were informed that participation was completely voluntary and would not affect any care if potential participants declined to take part or withdraw at any stage.

Participants who agreed to take part in the study were encouraged to keep the patient information leaflet as a source of reference and contact details of the research team if questions arose post completion. Each participant had the time to ask questions about the patient information sheet and the researcher highlighted the key aspects of the patient information sheet and the reason for the research. Once participants had informed a member of the research team that they agreed to take part in the study, a member of the research team asked the

participant to complete a written consent form (Appendix Six) outlining the different aspects of consent and data protection. The consent form was also signed by the member of the research team. Participants were also informed that the study was completely confidential, and each participant was issued with a unique ID number which was added to the consent form and all subsequent instruments and paperwork. The data collected was to be stored for a minimum of seven years and held within the research team's locked office.

Once consent was given and signed by both the researcher and participant, the participant was then asked to complete a demographics sheet (Appendix Four) which asked a number of standard questions on age, date of birth and smoking history. Participants were then asked to undertake a spirometry test. If participants declined at this point or recently had a spirometry test at their General Practitioner (GP) or hospital, a letter was sent to the GP/Hospital requesting a copy of this spirometry if undertaken within 1 year.

Once demographic details and spirometry were obtained by participants, they then were asked to complete questionnaire 'Pack A' which consisted of the preliminary 38 itemed COPD PREM questionnaire plus a number of other outcome measures (Table 5.2). Once completed participants were then asked to complete 'Pack B' consisting of the preliminary 38 itemed COPD PREM and a global rating of change questionnaire. Participants were then asked to complete the two questionnaires one week later and return to them to the researchers' office. A stamped addressed envelope was included for this purpose. The aim was to achieve a 20% return (Jones et al., 2012).

Table 5.2
List of other outcome measures identified

Outcome Measures
Demographics*
Smoking Status
Spirometry
Pack A **
COPD PREM-38 Questionnaire
COPD Assessment Test (CAT)
Hospital & Anxiety Questionnaire
MRC Dyspnoea Scale Questionnaire
Pack B
COPD PREM-38 Questionnaire
Global Rate of Change Questionnaire**
Stamped Address Envelope
* Age / Gender
** Appendix Seven

5.3.5. Ethics

NHS ethical approval was obtained from Bloomsbury Research and Ethics Committee (Appendix Eight). As a number of different institutions and organisations were also involved, ethical approval or consideration was also received from the following (Appendix Nine):

- University of Portsmouth;
- Local Research Ethics Committee of the Region;
- Research & Development approval at participating NHS sites;
- British Lung Foundation approval letter.

Ethical approval was obtained from the acute trusts that covered the specific hospital from which participants were recruited. Ethical approval and permission from the British Lung Foundation to approach Breathe Easy groups was also sought

There are a number of the items on the PREM instrument which are potentially ethically sensitive statements regarding the 'future', and therefore the research team were made specifically aware that participants were to be informed of these and an opportunity to discuss them further was provided at the time or within the patient information sheet. The research team advised participants to speak to their local respiratory nurse or to contact the Chief Investigator if they should wished to discuss any aspect further.

5.4. Methods of Data Collection

All participants that consented were issued with a unique ID number this was added to all self-reported instruments and on any correspondents about the participant.

5.4.1. Instrument data

The 38-itemed COPD-PREM along with three commonly used outcome measures in COPD care were used for data collection. This formulated part of the reliability and validity process of the item generation, along with a correlation across these outcome measures, this being a secondary objective (numbers four and five on page 107) of the study. All outcome measures used within this study have research reliability and validity and are widely used within current respiratory research including COPD (Puhan,et al., 2010). The outcomes allow for meaningful data

of participants with COPD and their response rate to completing instruments. Outcome measures included are highlighted in Table 5.2 and points of measurement are highlighted Figure 5.2 (Recruitment process map).

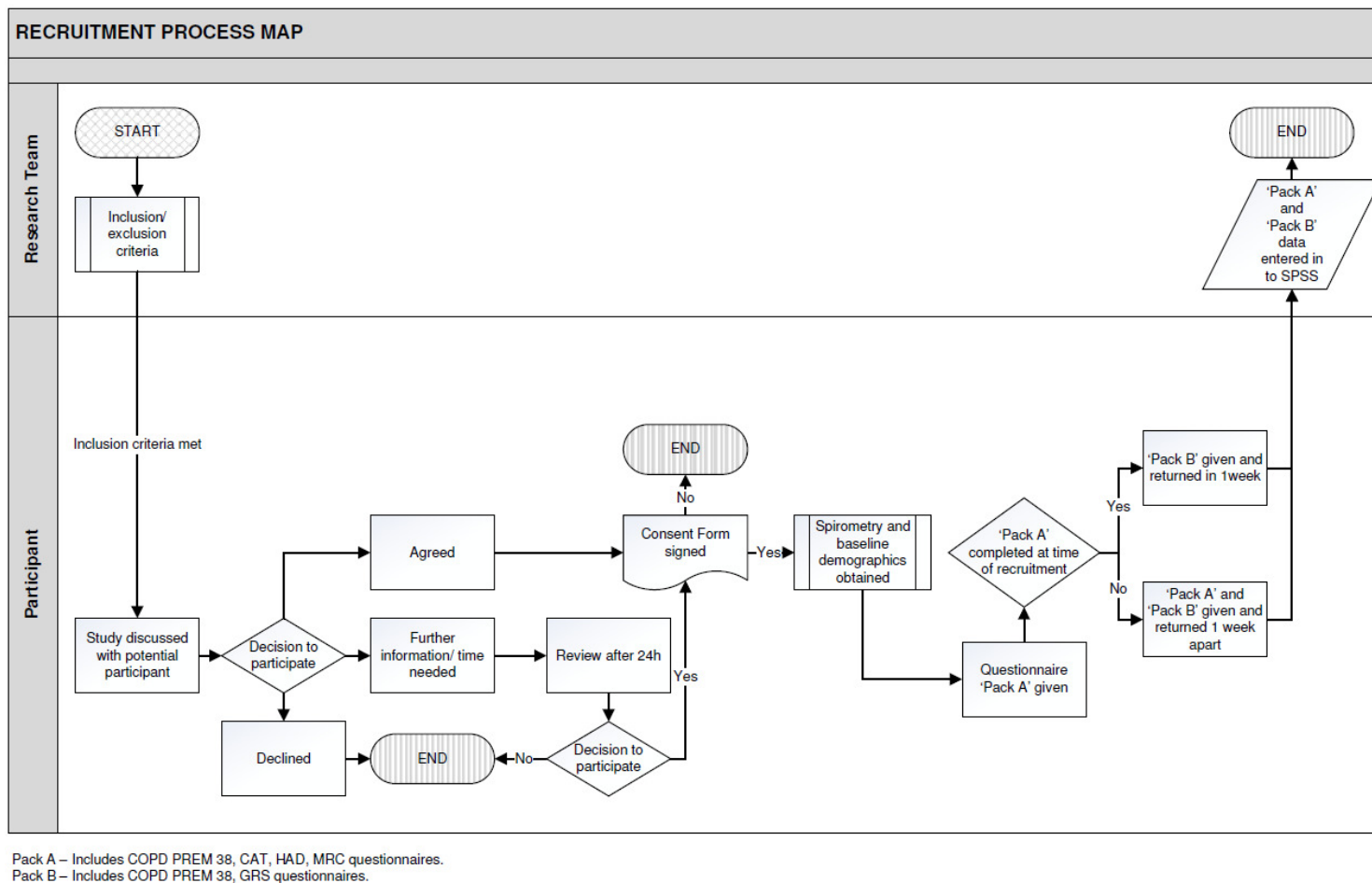


Figure 5.2 Recruitment process map

Participant recruitment and study flow is outlined in the recruitment process map Figure 5.2. For NHS recruitment the following protocol was conducted:

1. A nominated healthcare professional conducted daily screening (Monday through to Friday) of patients admitted to the hospital with an acute exacerbation of COPD. They conducted screening of outpatients attending pulmonary rehabilitation clinics (time and days varied dependent on activity) and community COPD patients;
2. A nominated healthcare professional approached eligible patients and their families prior to discharge, or earlier dependent on how unwell the patient was. They described the study and invited the potential participant to take part in the study. If, during screening, the patient did not fit the inclusion criteria the patient was not entered on to the study;
3. The nominated healthcare professional administered and signed a consent form along with the participant. Pack A (Table 5.2) was given to the consenting patient;
4. Participants then had three options to do the following:
 - a. take Pack A home with them and return the questionnaires in a stamped address envelope to the participating NHS organisation, or, where it was a Breathe Easy Group, send all instruments back to the CI organisation as the chief investigator of the study;
 - b. take Pack A home and return the completed pack to the pulmonary rehabilitation or COPD clinic from where the participant was recruited;

- c. complete Pack A 'there and then' (preferred option) and complete Pack B (COPD-PREM and global rate of change instrument) sent back to the Chief Investigator one week later in the provided SAE.
5. Throughout the process, regardless of which option of completing the instrument packs, the consent, spirometry and demographic data had to be completed at the time of recruitment. All instruments were labelled with the participants' unique letter and number code.

Participants recruited from within the Breathe Easy Groups were self-selected and follow the same steps from 3 to 5.

5.4.2. Research Instruments for Data Collection

COPD Patient Reported Experience Measure (PREM) Instrument

The 38-itemed COPD-PREM instrument developed as part of a stage one was included as the instrument in development. Each participant was asked to complete this and choose a score from zero to five. A low score suggested more positive experience the higher the score suggestive of a higher negative experience.

Medical Research Council Dyspnoea Scale (MRC)

The Medical Research Council scale (Appendix Seven) is a self-reported measure of dyspnoea intensity. It is a simple five point scale which has been validated and is a widely accepted tool to use within COPD (NICE 2004). The scale is used to assess severity of disease or monitor symptom severity by an assessment of tasks that incite dyspnoea or functional disability that results from dyspnoea (Fletcher, 1960). The scale allows the patient to point out the degree of dyspnoea that

affects their mobility. Participants were then asked where they thought they were on the MRC scale on the day of the assessment and this response was then recorded.

Hospital Anxiety and Depression Questionnaire (HAD)

The Hospital Anxiety and Depression Scale (HADS) (Appendix Seven) was designed to detect symptoms of anxiety and depression through a scoring system and a series of questions relating to usual activities which may reflect a higher degree of anxiety or depression, or both. It is a well-validated tool for measuring an increasing issue within COPD care and is designed to measure changes in symptoms over time (Garrod, Marshall, Barley, & Jones, 2006).

COPD Assessment Test (CAT)

The COPD Assessment Test (Appendix Seven) is designed to offer a measurement of the impact of COPD on a person's health. It is a short, validated questionnaire comprising of 8 questions that relate to a variety of different aspects of COPD and its effects on health status. The main aim of the questionnaire is to support and guide healthcare professionals gauge a better understanding of how COPD is currently impacting the patient in order to help tackle these issues and progress the management of COPD and improve the quality of care (Jones et al. 2009).

Global Rate of Change (GRC)

The Global Rate of Change questionnaire (Appendix Seven) is a simple questionnaire that is designed to detect changes in patients' health status over a period of time. Patients were asked to consider if there had been an improvement or a deterioration in health status since completing the first set of

questionnaires. This type of questionnaire is usually used in clinical practice to assess 'intervention' and quantify to healthcare professionals any changes in medical or therapy management for the patient (Rabe et al., 2007).

5.5. Data Analysis – Phase I

This study adopts a test-retest questionnaire development design aimed to develop a new COPD PREM instrument. The aim of data analysis is to assess the instruments reliability and validity, ensuring constancy of data and identify the most reliable and valid items to be included in the final PREM-COPD (Rattray & Jones, 2007).

5.5.1. Summary of demographics

Firstly a summary of the baseline demographic characteristics of participants was undertaken using descriptive statistics including the mean and standard deviation values for age, gender and FEV₁ % predicted. This data was then taken from the demographic sheets and entered onto the SPSS Statistics v.20 (Statistical Package for the Social Sciences). This is a formal statistical package for the analysis of results and is widely used by researchers (Polit, 2010, p.374). The demographics, including age, gender, FEV₁%, MRC and the results of the questionnaires and preliminary COPD-PREM were also recorded and entered into SPSS. This section supports objective two of the overarching research objectives set (p.103) and is phase one of study two.

5.5.2. Hierarchical Item Reduction

A formal approach to the first stage of item reduction was used following a series of different statistical approaches and following a traditional psychometric theory

(Hand., 2011). The items for potential reduction were focussed on generating a reliable and meaningful measurement that reduced bias and therefore generate more concise and appropriate instrument. Using the SPSS computer software, a number of statistical tests were undertaken to formulate a structured plan of item reduction. Below is the protocol overview of each item reduction method:

1. Firstly, age bias was explored against the total items. This is a statistical test that assesses the correlations between age and the each item in an instrument. It can be measured using a Spearman's rho or Pearson's Correlation coefficient, dependent on whether data entered is parametric or non-parametric. The reason this test is carried out is in order to find out whether there are any items that have a specific correlation against age. For example, does a certain item appear more often with a certain age group? The reason this is important is to ensure that all items answered across the age spread are not biased by a certain age group. For the purpose of this study Spearman's rho was used and Items identified with a p value ($p < 0.05$) were excluded as part of the item reduction phase of this study;
2. Items were also tested for gender bias against the total items. This is a statistical test which assesses the differences in response between male and female answers and within each item in an instrument. It can be measured with a t-test or a Mann-Whitney U ($p < 0.05$) test dependent on whether the data is parametric or non-parametric, but essentially two unpaired groups are being compared and measured. The reason this test is carried out is to find out whether there are any items that show a more favourable answer to males over females or vice versa. This test is

important is to ensure that both genders and all items have been answered equally across both groups, therefore reducing a gender bias. A Mann-Whitney U test was completed and Items identified with a p value ($p < 0.05$) were excluded at this item reduction phase of the study;

3. It is normal with instrument development that participants do not complete every item in the questions asked (Jenkinson et al., 2002). Removal of missing data is undertaken. This test ensures that items where there are large amounts of missing data are removed from the item list as part of the item reduction process. For this study this was set at 15%;
4. The incidence of maximum (ceiling) and minimum (floor) scores for each items were recorded. A significant concern in healthcare measurement is the extent to which an instrument displays a lack of sensitivity to change the extremes of the distribution, known as floor and ceiling effects. Ceiling effects are reported when there is variance in measuring an independent variable. And where a ceiling effect occurs, when you have answered the highest discriminatory value possible within the scale of an instrument. For example, in the preliminary COPD PREM using a scale of 0-5, and select the percentage of the participants reported a five score. However, you cannot be clear whether the participants response was five or potentially could have been higher but as a ceiling affect was reached therefore the exact level of their answer cannot be determined (Wang et al., 2009).

When gathering data from the instrument this means that you potentially may have a group of participants who are answering at the upper end of the scale, thereby a ceiling affect is reported. Therefore, an item could be

introducing bias as it may not represent the true population sample. A floor effect is the opposite to this, when the lower scale number is reported. In this study such items may detract from the instrument's psychometric properties, because they were not selected by the majority of the participants. These items therefore fail to discriminate between patients with different experiences in COPD. Because such items make the instrument longer to complete, these items were deleted (Jones, et al. 2009) A floor to ceiling effect > 40% was set and any items above this were deleted.

5. The item to item correlation is a statistical test to demonstrate where certain items are correlated to each other and therefore the results potentially may be similar. Results are expressed as an r value. Items with a value greater or equal $r=0.80$ were removed from the main item list.

After the final items were identified these then were entered into the Rasch Model following a expert group discussion.

5.5.3. Face Validity

Following the hierarchical item reduction a pool of items remained. These remaining items went through a face validity process with an expert panel and feedback from participants. A number of potential items were then also deleted further and a set number of items remained. After this process the remaining items were further scrutinised in the Rasch phase.

5.6. Rasch Phase

Following the hierarchical item reduction and face validity, the pool of items that survived this process was entered into the RUMM2030 (Rasch Model 2030) package where a further set of statistical tests scrutinised these items further using

the Rasch analysis. The process of item removal in Rasch is an iterative process however there is no clear set of processes and parts of the process do not happen in a uniform way. The data entered into RUMM2030 were polytomous data, this means that the model sees the thresholds between categories as the same across all items entered (Tennant & Conaghan., 2007, p.5). The main objective of the Rasch model is to test how well the observed data fit the expectations of the measurement model.

Once the data were entered into RUMM2030, failure of items to fit the model led to a precise number of actions using a range of techniques (Mills et al., 2010) as there is no one single test that can be used to examine the data and the model relationship in Rasch (Hagquist, Bruce, & Gustavsson, 2009). Therefore a number of tests were undertaken to explore the data and to understand the current fit to the model. These will be explained further over the next few pages.

5.6.1. Ordering of response categories – Thresholds

The threshold ordering of polytomous items examines the category structure. This, in short, examines whether the responses to the items are consistent with the metric estimate of the underlying construct and is ordered in a number of category responses. If disordered data appears, as in this case, then items were needed to be rescored and categories collapsed.

For a polytomous scale, the ordering and distance of response categories for each item is measured by exploring the threshold between each of its response categories. If the response options are correctly ordered, the probability of endorsing mild options should increase in a logical manner according to the level of experience of each participant.

Threshold ordering (i.e. the transition between two points) was compared in RUMM2030 by checking the class interval distributions. This allowed each item and their responses to cross a threshold and whether there was a natural continuum of responses for an ordered threshold. The thresholds correspond with the threshold points between two different scores, at this point it is likely to obtain either score (i.e. for a specific item, the point which the probability is a one on the item or a two on the item is 50/50).

A disordered threshold meant that the item is not working properly, that is, the current scoring categories are not progressing in a logical order. Therefore, some items had to be collapsed and rescored (Pallant and Tennant, 2007).

5.6.2. Class Intervals (CIs)

Participants were automatically be placed into groups once the data had been entered into the Rasch Model. These groups are called class intervals and are defined by the experience within each item. This is highlighted further in the results section.

In RUMM2030, participants are ranked automatically and placed in groups and divided into CIs of approximately equal numbers. This ensures that the mean observed scores for each class interval are then compared to a number expected by the Rasch model. This then divides all patients into groups dependent on the severity of COPD.

5.6.3. Tests for individual item fit

In Rasch there are several different ways to explore item fit. Individual item fit refers to the ability of each item to discriminate between patients with different

levels of experience. Tests of item fit to the model reflect the differences between the observed responses and that expected by the Rasch model. These are presented as residuals and as a Chi-Square probability statistic within chapter six of the results.

Fit investigations begin by examining the residuals – the difference between the observed score and the expected score – for a particular person and item. A fit residual is a summation of individual person and item deviations from model expectations. Item residuals between ± 2.5 are considered to show a sufficient fit to the model. Negative residuals indicate over-discriminating items and are usually linked with a high Item-Total correlation in CTT. This indicated the redundancy of a particular item.

Positive residuals indicate under-discriminating items. Individual item fit was also viewed graphically, using the Item Characteristic Curve (ICC). The ICC plots the model fit for each class interval (black dots) against the expected model curve and examples of the ICC are highlighted in the results chapter.

A Chi-Square statistic was used within RUMM2030 which compared the difference between the observed experience values with expected values across the class intervals for each item. A non-significant Chi-Square statistic greater than $p=0.05$, or Bonferroni adjusted value suggests a good fit to the Rasch model. The Bonferroni adjustment in this methodology involves dividing the original α -level (0.05) by the number of times a statistical test is repeated. Within the RUMM2030 model this is done automatically for every statistical test individual. If an item demonstrated a significant Chi-Square statistic then it is considered to misfit the Rasch model expectations and it was removed from the overall model

and item list. This process was repeated several times and items deleted to get a final negative Chi-square statistics as part of the overall fit statistics.

5.6.4. Summary of Item Removal using Rasch modelling

Throughout this methodology chapter it has made reference to a number of potential ways in which a number of item are removed either through the Hierarchical methods of item reduction or deleted through the Rasch analysis as ill-fitting items do not fit the overall unidimensional model of Rasch. This becomes clearer in chapter six of the results.

5.7. Reliability & Validity of the final item Phase – Phase II & III

In chapter four the concept of instrument reliability and validity was indicated in the development of any new instrument and fulfils the primary objectives three-five of the researchers study (p.103). Therefore the final aspect of the data analysis, post the Rasch model, was the final steps undertake to test the preliminary reliability and validity of the final items generated from the Rasch model. The steps involved in this testing are described below.

5.7.1. Reliability

Person Separation Index (PSI)

In RUMM2030 the Person Separation Index (PSI) is used for statistical purposes which is an estimate of the internal consistency of the scale known as the PSI. It is an equivalent measure and has similar traits to Cronbach's alpha. A PSI of a minimum value of 0.85 is needed for individual use (Tennant & Conaghan, 2007, p1361). This is shown and reported on within the results section.

Test-retest

As previously mentioned a test-retest of the items was undertaken. This takes the measurement of the same instrument but compares the results of the two instruments at two different time points, in this case one week apart. For the purpose of this study participants were encouraged to complete a second COPD-PREM one week after completing the first instrument. Participants were also encouraged to complete the Global Rate of Change questionnaire as previously mentioned. The results of the test-retest are presented in the results chapter.

5.7.2. Validity

Face Validity

Face Validity took place as part of the validity stage with participants from a number of different locations and included participants from pulmonary rehabilitation groups and Breathe Easy Groups. This ensured that patients with COPD were able to review the proposed final item and ensured that at 'face-value' it measured what the aim of the study proposed.

Content Validity

To examine content validity the preliminary COPD PREM (after Rasch analysis) was taken and reviewed by an expert research panel consisting of respiratory professors, respiratory academics and clinicians familiar with instrument development and Rasch analysis.

Concurrent Validity

To examine concurrent validity of the reduced preliminary COPD PREM instrument was tested using the Pearson's coefficient and applied to test

differences between the new preliminary COPD PREM and the COPD Assessment tool and Hospital Anxiety and Depression Scale. These are accepted and widely used PROMs used in COPD care (Jones et al. 2009) These results are reported along with the other aspects of validity in Chapter Six.

5.8. Chapter Summary

This chapter has given a detailed overview of the Study Two research study plan including the key stages to the design, recruitment of participants and the item reduction protocol using a hierarchical item reduction and item securitisation within the Rasch analysis. The final phase introduces the reader to the reliability and validity of the final preliminary item set and subsequent testing of this COPD PREM instrument against other patient reported outcomes frequently used within COPD care and research. It also highlights how the research objectives outlined in Chapter Three are being undertaken in the three phases of this thesis.

CHAPTER SIX

CHAPTER SIX

6. Results

6.1. Introduction

The previous chapter on methodology and methods gave a concise overview of the process of developing a new instrument and the number of steps taken to generate results, and the further development and refinement of the COPD-PREM. This chapter will present the results of the both the hierarchical item reduction and of the Rasch analysis. These methods are designed to reduce patient burden by removing redundant items and developing a more concise instrument. This section relates to the results of Study Two and the primary objectives of two to five (p.103). Initially, the participants' characteristics will be described, followed by the method results outlined in Chapter Five on the process of reducing the pool of 38 items, to a core set of items using the hierarchical methods and Rasch modelling (Rasch, 1960). A final core group of items will then be presented known as the COPD PREM-9.

6.2. Participant Characteristics

A total of 228 patients were approached to take part in the study. 40 declined to take part for a number of different reasons which included initial interest, but then refusal to take part. The other reasons being are too many questions, time, language and unwell. A further 14 participants agreed to take part, consented and took the questionnaire packs, but failed to return them. For that reason they had to be removed from the study. Therefore, a total of 174 patients was recruited into

the study; their baseline characteristics are shown in three groups highlighted in Table 6.1:

1. total number of recruited participants (All);
2. recruited from secondary care, PR and home (Hospital);
3. recruited from Breath Easy Groups.

Table 6.1
Baseline characteristics of all COPD patients included in the study

	1 All	2 Hospital	3 Breathe Easy
	N = 174	N = 86	N = 88
Age, years (Mean \pmSD)	71 \pm 9.1	71 \pm 9.8	71 \pm 8.4
Gender			
Male (%)	83 (48%)	45 (52%)	38 (43%)
Female (%)	91 (52%)	41 (48%)	50 (57%)
Smoking status, number			
Active smokers	20 (12%)	16 (19%)	4 (4%)
Ex-smokers	125 (72%)	51 (59%)	74 (84%)
Not disclosed	29 (16%)	19 (22%)	10 (12%)
Spirometry			
FEV₁ (% predicted) (Mean \pmSD)	59 \pm 21.9	53 \pm 22.3	48 \pm 21.3
FEV₁ % /FVC (Ratio) (Mean \pmSD)	50 \pm 20.4	53 \pm 17.2	67 \pm 21.4
NICE classification*†	% (n)		
Mild	23 (13)	12 (13)	11(13)
Moderate	46 (26)	27 (31)	19 (21)
Severe	50 (29)	32 (37)	19 (21)
Very Severe	26 (17)	11 (13)	15 (18)
Outcome measures			
Medical Research Council (MRC) (Mean \pmSD)	3.4 \pm 1.0	3.5 \pm 1.1	3.3 \pm 1.0
COPD Assessment Tool (CAT) (Mean \pmSD)	20 \pm 8.5	23 \pm 9	21 \pm 7.8

Anxiety Score (Mean \pmSD)	7.6 \pm 4.1	7.8 \pm 4.1	7.3 \pm 4.2
Depression Score (Mean \pmSD)	6.1 \pm 3.9	6.3 \pm 3.8	5.8 \pm 3.9
Data shown represented mean \pm SD unless otherwise indicated FEV ₁ : Forced expired volume in one second; FVC: Forced vital capacity *NICE (2010) Classification † Only 145 people with spirometry information			

There was an even distribution between the two groups in which the Packs were completed. English was the first language for most people completing the pack but this was not recorded. All patients had a confirmed diagnosis of COPD. Participants were recruited from a number of different locations across England and the Channel Islands (Table 6.2).

Table 6.2
Recruitment sites of participants

Recruitment Site	N
London	120
Manchester	15
Guernsey	8
Essex	5
Norwich	7
Portsmouth	19

6.2.1. Missing Data

Overall, there was less than 10% missing data, except spirometry, which was recorded at 25%. There were a number of questions in the item-list that demonstrated a high level of missing data including item 4 relating to smoking (76%) and item 15 on COPD Tablets (28%). These two items were removed

as part of the item reduction protocol. Less than 2% of participants failed to complete the additional questionnaires (CAT, HAD and MRC). To account for missing data 'exclude cases pair wise' was selected in SPSS. This is an acceptable exclusion criteria for excluding the participant only if they were missing the data required for a specific analysis (Pallant., 2010).

6.3. Hierarchical Item Reduction – Summary of results

The hierarchical item reduction process will now be shown for each step and the items that were removed. A final table showing all items deleted and the reasons for this will be shown at the end of this section in Table 6.3.

Table 6.3
Overview of item reduction results

Q No	Question (Low Score Answer)	Missing >15%	Floor > 40%	Age Correlation	R Value
1	I am not shocked by my COPD diagnosis				
2	I have come to terms with my diagnosis of COPD				
3	I have given up smoking and I am confident that I will not start	X			
4	I want to stop smoking and I believe I can	X			
5	It was a relief to have a diagnosis for my symptoms	X			
6	I understand my diagnosis		X		
7	I am confident that my GP will listen to my point of view				Q13
8	I am very pleased with health care workers		X		Q13
9	I am happy with the length of time to see GP				
10	I really enjoyed pulmonary rehabilitation	X			Q11
11	I found pulmonary rehabilitation useful	X	X		Q11
12	I understand my condition and this helps me to manage my fear			X	
13	The information I have been given is consistent		X		Q8
14	I have enough information about my condition		X		
15	I understand about my COPD tablets	X			
16	I am confused about how to use my COPD inhalers				
17	I understand how my COPD treatments work		X		
18	I don't find going to a hospital outpatient clinic frustrating				
19	I know how to use my inhaler properly		X		
20	I have accepted the limitations to my lifestyle caused by COPD				

21	I feel that I have good support from others		
22	Overall I am satisfied with my life		
23	I am not depressed		
24	Overall I am satisfied with the care given to me	X	
25	I am not embarrassed to tell others about my condition	X	
26	I feel that I am in control of my condition		
27	I am motivated to keep going and to not give up	X	
28	I am happy to talk about the future	X	
29	I am not concerned about the future		X
30	I am not worried about the season		X
31	I keep going and try to enjoy my life	X	X
32	I am confident in a 'flare up' I have quick access to treatment		
33	I do not feel anxious about my current health		X
34	I am not worried about the care I will get with 'flare-up'		
35	I am not scared of getting a cold or an infection		X

6.3.1. Age Bias

Items which had an age bias towards items from the initial 38-item pool were removed using a p value < 0.05 . This process resulted in six items being removed. Table 6.4 summarises the lower scored answer items. These six items were removed.

Table 6.4
Items removed due to age bias

Q	Question (Low Score Answer)	Spearman rho*	Remove
12	I understand my condition and this helps me to manage my fear	0.007	X
29	I am not concerned about the future	0.012	X
30	I am not worried about the season	0.017	X
33	I do not feel anxious about my current health	0.002	X
35	I am not scared of getting a cold or an infection	0.037	X
36	I am not frightened of being breathless when I have a 'flare-up'	0.002	X
* p value < 0.05			

6.3.2. Gender Bias

Items demonstrating gender bias towards items from the initial 38-item pool were removed at this initial point. This process resulted in one item being removed (Table 6.5).

Table 6.5
Items removed due to gender bias

Q	Question (Low Score Answer)	Mann Whitney – U (p value)*	Remove
35	I am not scared of getting a cold or an infection	0.010	X
* p value < 0.05			

6.3.3. Removal of items with >15% missing data

Items which had missing data for more than 15% were removed from the item list. This process resulted in six items being removed (Table 6.6).

Table 6.6
Items removed due to missing data

Q	Question (Low Score Answer)	Missing (%)*	Remove
3	I have given up smoking and I am confident that I will not start	19%	X
4	I want to stop smoking and I believe I can	76%	X
5	It was a relief to have a diagnosis for my symptoms	17%	X
10	I really enjoyed pulmonary rehabilitation	18%	X
11	I found pulmonary rehabilitation useful	17%	X
15	I understand about my COPD tablets	28%	X
* missing data >15%			

6.3.4. Floor and ceiling effects > 40%

No items were eligible for removal for ceiling effects (i.e. more than 40% of participants) scoring the item. Twelve items were removed for floor effects (i.e. more than 40% of participants) scoring the item a zero (Table 6.7).

Table 6.7
Items removed due to floor effect

Q	Question (Low Score Answer)	Missing (%)*	Remove
6	I understand my diagnosis	47%	X
8	I am very pleased with health care workers	46%	X
11	I found pulmonary rehabilitation useful	44%	X
13	The information I have been given is consistent	44%	X
14	I have enough information about my condition	43%	X
17	I understand how my COPD treatments work	40%	X
19	I know how to use my inhaler properly	55%	X
24	Overall I am satisfied with the care given to me	46%	X
25	I am not embarrassed to tell others about my condition	53%	X
27	I am motivated to keep going and to not give up	49%	X
28	I am happy to talk about the future	44%	X
31	I keep going and try to enjoy my life	49%	X
* floor effect >40%			

6.3.5. Item to item correlation

The final process before Rasch analysis was to remove items that correlated with another item within the instrument. This was undertaken using a spearman's rho measure to identify the relationship is between two variables. Four of the 38 items had a positive r value ($r > 0.80$) and therefore were removed (Table 6.8). Table 6.8 summarises the lower answered experience item. These four items were also highlighted for removal in earlier tests.

Table 6.8
Items removed due to item to item correlation

Q	Question (Low Score Answer)	Spearman's rho*	Remove
8	I am very pleased with health care workers	0.83	Q13
10	I really enjoyed pulmonary rehabilitation	0.83	Q11
11	I found pulmonary rehabilitation useful	0.83	Q11
13	The information I have been given is consistent	0.83	Q8
* r value > 0.80			

There was one additional item, item no. 7 ('I am confident that my GP will listen to my point of view') with a high Spearman's value (0.83), which suggested it correlated with item 13 ('the information I have been given is consistent'). This item remained as the research team felt that the two items did not necessarily match or measure the same area and therefore item 7 was retained as this was relevant to patient experience.

6.3.6. Overview of Questions Removed

From the original 38 items listed, 22 items were removed (Table 6.9) following the hierarchical item reduction, which meant 16 items remained for further analysis in the Rasch model.

Table 6.9
List of items removed and retained

Q	Question (Low Score Answer)	Removed Item	
		Yes	No
1	I am not shocked by my COPD diagnosis		X
2	I have come to terms with my diagnosis of COPD		X
3	I have given up smoking and I am confident that I will not start	X	
4	I want to stop smoking and I believe I can	X	
5	It was a relief to have a diagnosis for my symptoms	X	
6	I understand my diagnosis	X	
7	I am confident that my GP will listen to my point of view		X
8	I am very pleased with health care workers	X	
9	I am happy with the length of time to see my GP		X
10	I really enjoyed pulmonary rehabilitation	X	
11	I found pulmonary rehabilitation useful	X	
12	I understand my condition and this helps me to manage my fear	X	
13	The information I have been given is consistent	X	
14	I have enough information about my condition		X
15	I understand about my COPD tablets	X	
16	I am confused about how to use my COPD inhalers		X
17	I understand how my COPD treatments work		X
18	I don't find going to a hospital outpatient clinic frustrating	X	

19	I know how to use my inhaler properly	X	
20	I have accepted the limitations to my lifestyle caused by COPD		X
21	I feel that I have good support from others		X
22	Overall I am satisfied with my life		X
23	I am not depressed	X	
24	Overall I am satisfied with the care given to me	X	
25	I am not embarrassed to tell others about my condition	X	
26	I feel that I am in control of my condition		X
27	I am motivated to keep going and to not give up	X	
28	I am happy to talk about the future		X
29	I am not concerned about the future	X	
30	I am not worried about the season	X	
31	I keep going and try to enjoy my life	X	
32	I am confident in a 'flare up' I have quick access to treatment		X
33	I do not feel anxious about my current health	X	
34	I am not worried about the care I will get with 'flare-up'		X
35	I am not scared of getting a cold or an infection	X	
36	I am not frightened of being breathless when I have a 'flare-up'	X	
37	I am not frightened to go to sleep 'flare-up'		X
38	I try not to panic when I have a 'flare up'		X

6.4. Face validity

Prior to the Rasch analysis and following the hierarchical item reduction a total of 16 items (Table 6.10) were retained. Face validity with these items by the research team along with the qualitative exploration of themed items was undertaken.

6.4.1. Face validity testing

Each item was then scrutinised for its use within an experience measure and for professional respiratory opinion, as well as feedback from participants who completed the questionnaire, regarding the question structure and the meaning of what it was perceived to measure was discussed and debated, the predominate feature was 'confusion' on how it could measure experience in COPD. This was

done in two rounds and a further three questions were deleted as a result in as outlined in Table 6.10.

Table 6.10
Items removed following face validity

Question No	Question (Low Score Answer)	Theme	1st Validity Screen*	2nd Validity Screen**
1	I am not shocked by my COPD diagnosis	Diagnosis	X	
2	I have come to terms with my diagnosis of COPD	Diagnosis		
7	I am confident that my GP will listen to my point of view	Primary Care		
9	I am happy with the length of time to see my GP	Primary Care		
14	I have enough information about my condition	Education		
16	I am confused about how to use my COPD inhalers	Education		
17	I understand how my COPD treatments work	General		
20	I have accepted the limitations to my lifestyle caused by COPD	General		
21	I feel that I have good support from others	General		
22	Overall I am satisfied with my life	General		
26	I feel that I am in control of my condition	Control		
28	I am happy to talk about the future	Future		
32	I am confident in a 'flare up' I have quick access to treatment	Exacerbation		
34	I am not worried about the care I will get with a 'flare-up'	Exacerbation		
37	I am not frightened to go to sleep 'flare-up'	Exacerbation		X
38	I try not to panic when I have a 'flare up'	Exacerbation		X
* 1 st Validity Screen – items removed				
** 2 nd Validity Screen – items removed				

In the first round, item 1 the 'diagnosis theme' was deleted as after reviewing comments from participants, several felt that because they had been diagnosed with COPD for many years now they were no longer shocked about their COPD diagnosis, and therefore chose to give item 1 a '0', 'I am not shocked by COPD diagnosis' or left it blank.

The two further items (37 & 38) were removed after exploring the item spread (Figure 6.1 & 6.2) across the COPD disease severity. Both items 37 and 38 did not correlate well across a wide distribution of COPD patients in severity and age.

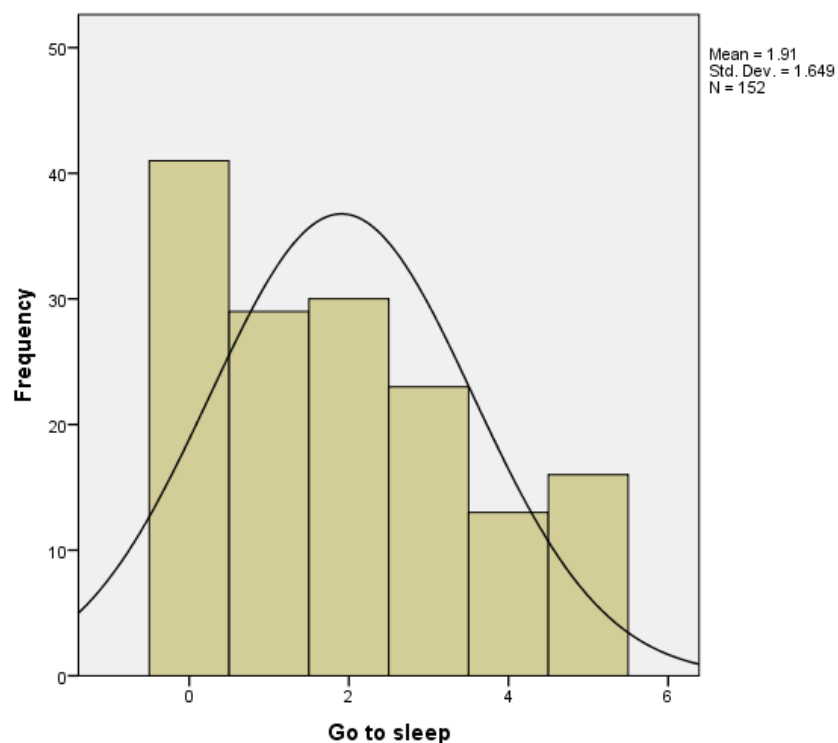


Figure 6.1 Poor distribution across severity of COPD for item 37

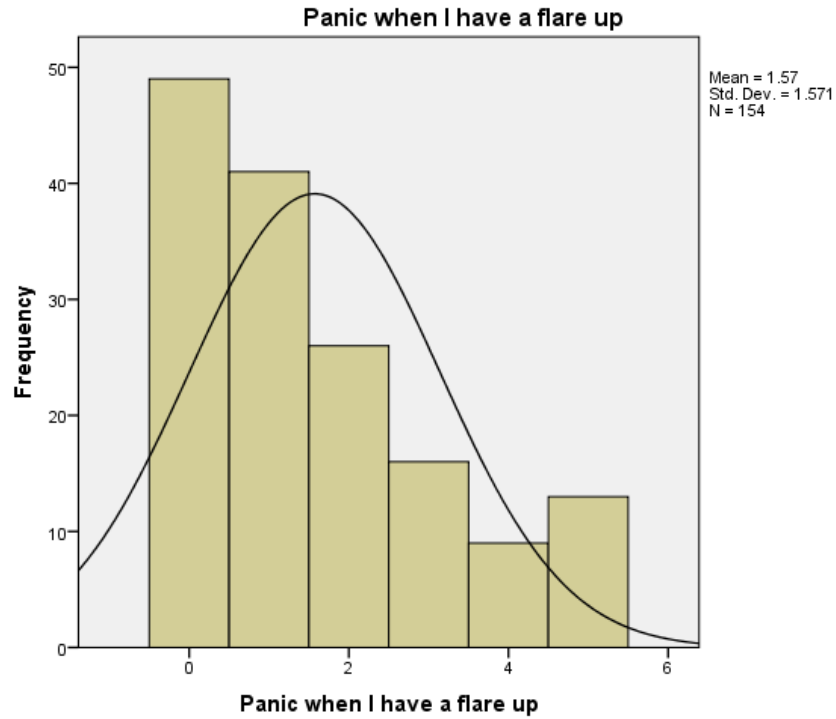


Figure 6.2 Histogram showing poor distribution across age for item 38

After the face validity outlined in section 6.4.1 a further three items were deleted from the remaining 16-item list. This therefore 13 items to be entered and reviewed further in the Rasch Model.

6.5. Rasch Analysis

6.5.1. Introduction

After the hierarchical reduction process, Rasch analysis was performed on the remaining 13 items (Table 6.11).

Table 6.11
Remaining 13 items entered into the Rasch Model

Q	Low Scoring Question (0)*	High scoring Question (5)**
2	I have come to terms with my diagnosis of COPD	I have not come to terms with my diagnosis of COPD
7	I am confident that my GP will listen to my point of view	I am concerned that my GP won't listen to my point of view
9	I am happy with the length of time that it takes to get an appointment with my GP when I need to	I am angry about the length of time that it takes to get an appointment with my GP when I need to
14	I have enough information about my condition	I am frustrated by my lack of information about my condition
16	I am confused about how to use my COPD inhalers	I understand how to use my COPD inhalers
17	I understand how my COPD treatments work	I am confused about how my COPD treatments work
20	I have accepted the limitations to my lifestyle caused by COPD	I am frustrated and unhappy by the limitations to my lifestyle caused by COPD
21	I feel that I have good support from others like my family, friends, neighbours or carers	I feel that I don't have any support from others like friends, family, neighbours or carers
22	Overall I am satisfied with my life	Overall I am very dissatisfied with my life
26	I feel that I am in control of my condition	I feel that I don't have any control over my condition
28	I am happy to talk about the future	Talking about the future makes me feel depressed
32	I am confident in a 'flare up' I have quick access to treatment e.g. a rescue pack or access to my GP	I am worried that in a 'flare up' I don't have quick access to treatment e.g. a rescue pack or access to my GP
34	I am not worried about the care I will get from health professionals when I get a 'flare-up'	I worry about the care I will get from health professionals when I get a 'flare-up'

6.5.2. Threshold Plot Map

There were a number of items that had a disordered threshold. Figure 6.3 clearly shows this by denoting items seven and nine with the ** symbols. In Rasch these items are not being scored in a logical order. Therefore, the disordered thresholds were collapsed appropriately to get a more appropriate fit as shown in Figures 6.4 and 6.5 which uses item 26 as an example to give a diagrammatic representation.

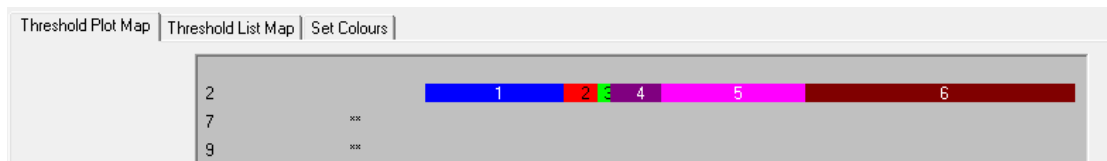


Figure 6.3 Threshold Plot Map showing a normal threshold (2)

The disordered and ordered thresholds are shown more clearly in 6.4 and Figure 6.5 as the results are plotted for each score in an item.

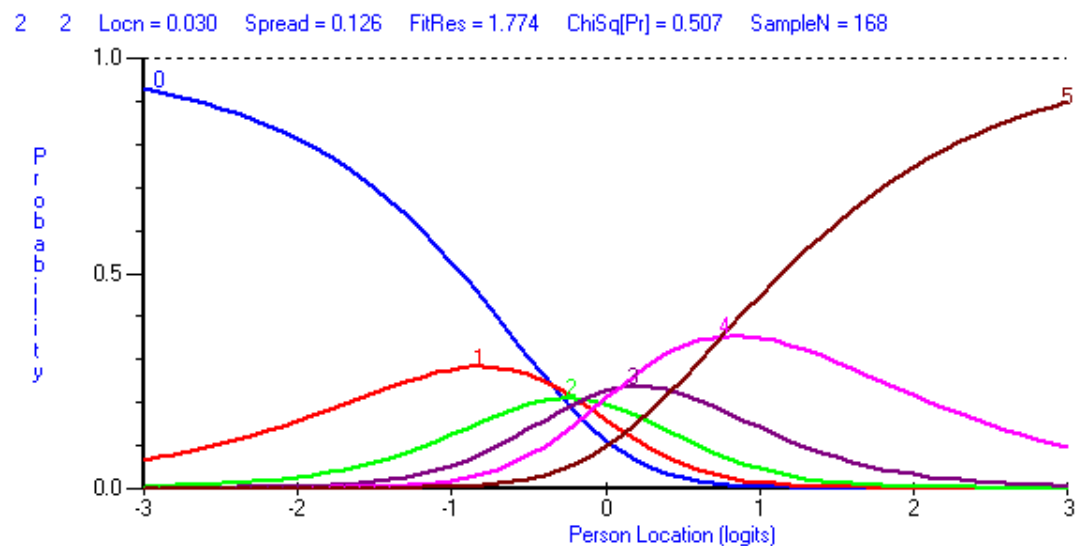


Figure 6.4 Example of a Disordered Threshold

Figure 6.4 is an example of a disordered threshold for item 2 '0 = I have come to terms with my diagnosis of COPD' and '5= I have not come to terms with my

diagnosis of COPD'. Figure 6.4 demonstrates that even when the likelihood of scoring a 1 is at its peak the probability is that a 0 will be scored instead.

Figure 6.5 is an example of an ordered threshold for item 26 '0= I feel I am in control of my condition' and '5=I feel I am not in control of my condition'

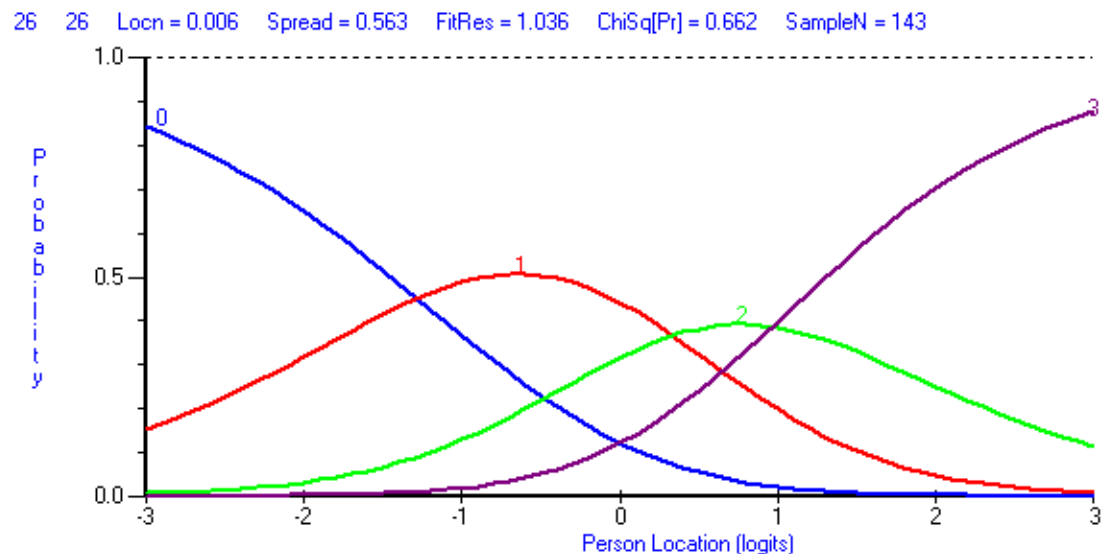


Figure 6.5 Example of an Ordered Threshold

The y-axis looks at the probability of a given response to an item and the x-axis represents the participants' experience expressed as a logit. The category response therefore is ordered in the appropriate threshold.

6.5.3. Class intervals (CIs)

In RUMM2030, patients are automatically placed into groups called class intervals (CIs). CIs are defined by ordering all patients in terms of experience and then splitting them into groups of approximately equivalent size of 50 persons in each group across the sample, in order to approximate groups. A number of fit statistics

are applied at the CI level (Hendriks, Fyfe, Styles, Skinner, & Merriman, 2012).

In this study the number of class intervals was 3 as shown in Table 6.12.

Table 6.12
Class intervals (CIs)

Item	CI*1	CI*2	CI*3
2	54	55	57
7	54	54	54
9	57	57	51
14	51	53	52
16	53	54	55
17	50	51	52
20	55	52	52
21	53	52	52
22	53	51	50
26	52	52	52
28	54	51	52
32	52	50	52
34	52	51	48
* 3 groups of Class Intervals			

This represents a good equal sample size in each of the Class intervals

6.5.4. Tests of individual item fit

Once all items have been re-scored the data can then be explored further looking at the item characteristic curve (ICC), which is a graphical representation of the data and this also gives further detail on why an item maybe not be fitting a model.

The ICC plots the model fit for each class interval (black dots) alongside the

accepted model curve as outlined in Figures 6.6, 6.7 and 6.8. There were a total of 3 items (2, 9 and 16). Also as mentioned in the Chapter Five a non-significant Chi-Square statistic less $p > 0.05$ would also suggest a good fit to the Rasch Model. Items 2, 9 and 16 will be highlighted as poor-fitting items to the Rasch Model with results shown. Figure 6.6 gives an example initially of an item fitting along the ICC.

6.5.5. Item 14 Example of well-fitting item characteristic curve

Figure 6.6 shows an ICC for a well-fitting item 14 'I have enough information about my condition' (low score question).

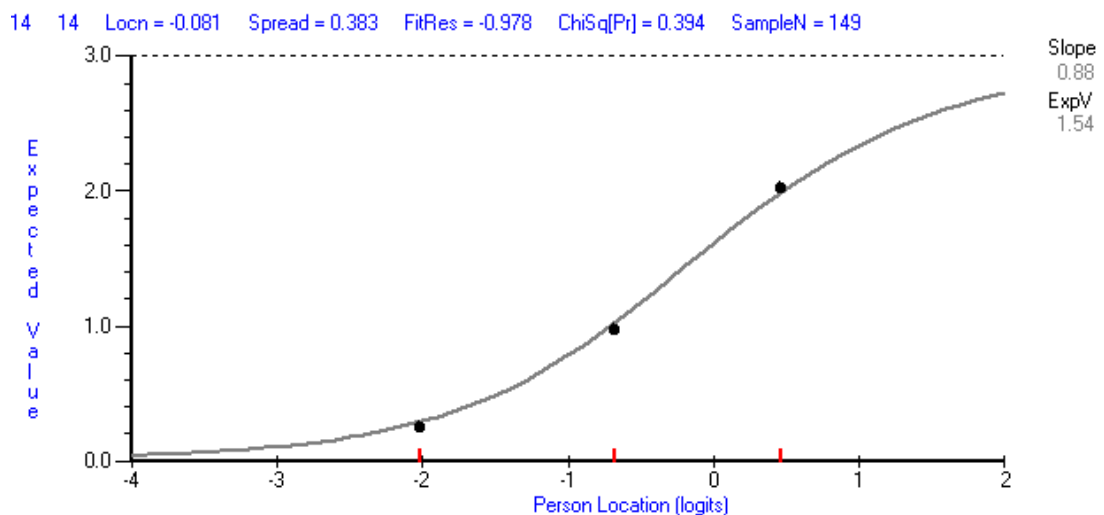


Figure 6.6 ICC for item14, a well-fitting item

The y-axis represents the item severity and the x-axis represents patient severity in logits. The curved line represents the expected scores for the item, and the dots represent the observed scores for the class intervals at the different severity levels. The fit residual (along the top) is +0.978 and the Chi-Square probability is 0.394, indicating no significant deviation between the expected and observed scores for this item.

6.5.6. Item 16 removal

Figure 6.7 is an ICC for item 16, a non-fitting item: 'I am confused about how to use my COPD inhalers (high score)'. This item is over-discriminating.

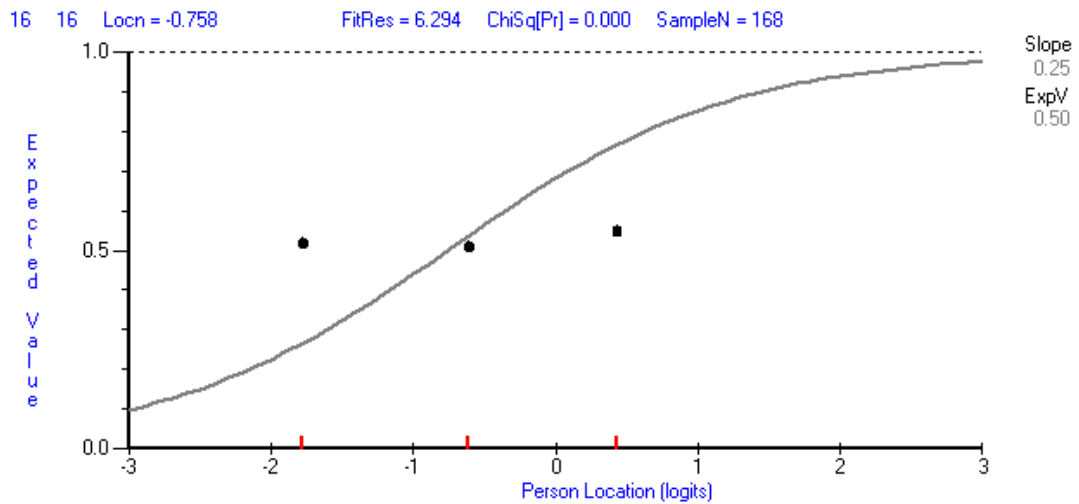


Figure 6.7 ICC for item 16, a non-fitting item

The observed scores (black dots) form a flatter curve than the expected scores (the curve). The fit residual for this item was 6.29 and a significant chi-square ($p=0.00$). This item was also disordered and had to be collapsed to 3 scores. This item was consequently removed.

6.5.7. Item 9 removal

Figure 6.8 shows an ICC for item 9, a non-fitting item: 'I am happy with the length of time that it takes to get an appointment with my GP when I need to' (low score).

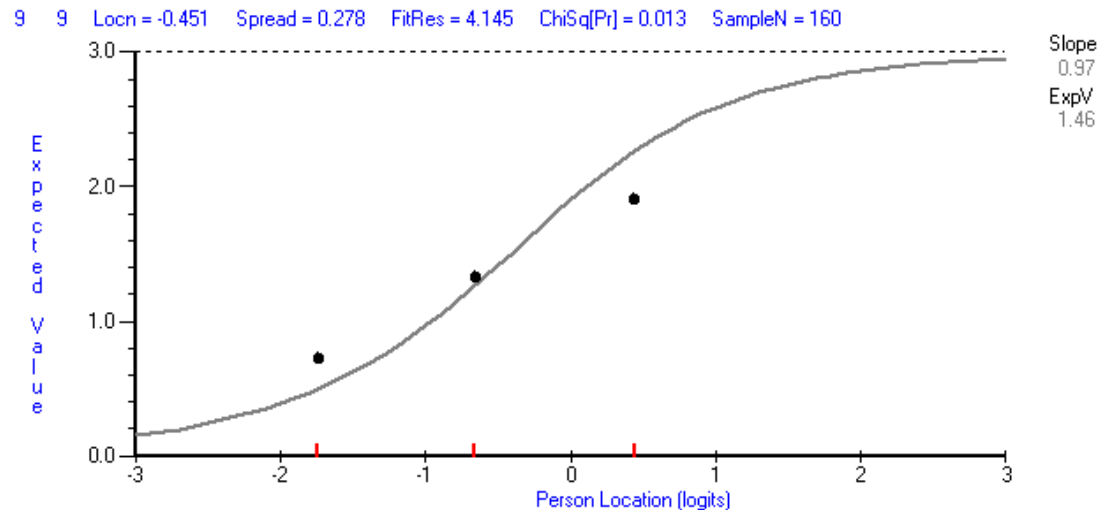


Figure 6.8 ICC for item 9, a non-fitting item

This item is over-discriminating – the observed scores (black dots) form a steeper curve than the expected scores (the curve). The fit residual for this item was 4.14 and it has a significant chi-square ($p=0.013$). This item was also disordered and had to be collapsed to 3 scores. This item was consequently removed.

6.5.8. Item 2 Removal

Figure 6.9 shows an ICC for item 2, a non-fitting item: 'I have come to terms with my diagnosis of COPD' (low score).

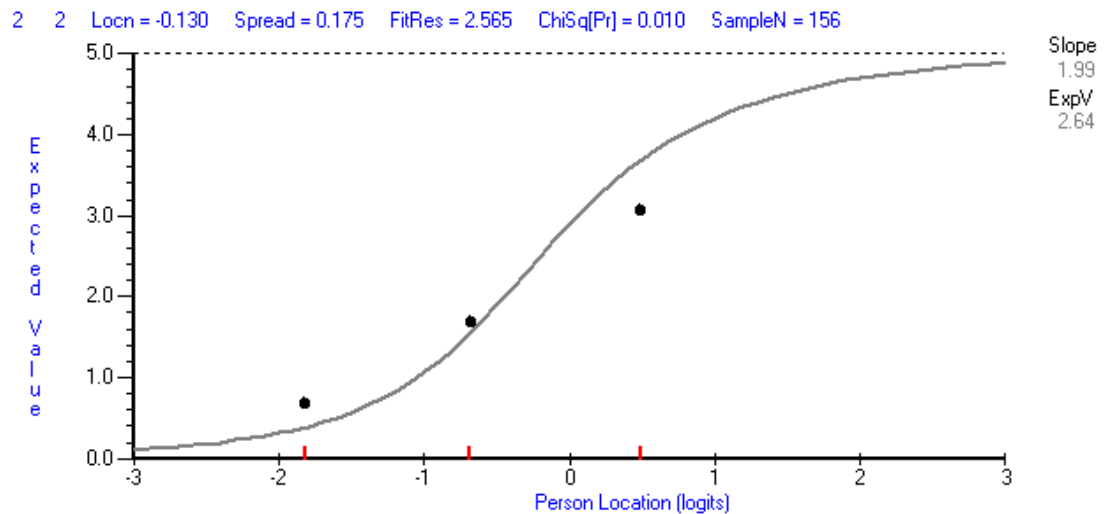


Figure 6.9 ICC for item 2, a non-fitting item

This item is over-discriminating – the observed scores (black dots) form a steeper curve than the expected scores (the curve). The fit residual for this item was 2.56 and it had a significant chi-square ($p=0.010$). This item was also disordered and had to be collapsed to 3 scores. This item was consequently removed.

Therefore there was a total of 10 items that had a fit to the overall Rasch model shown in Table 6.13.

Table 6.13
10 items with Rasch Fit

Q	Low Scoring Question (0)*	High scoring Question (5)**
7	I am confident that my GP will listen to my point of view	I am concerned that my GP won't listen to my point of view
14	I have enough information about my condition	I am frustrated by my lack of information about my condition
17	I understand how my COPD treatments work	I am confused about how my COPD treatments work
20	I have accepted the limitations to my lifestyle caused by COPD	I am frustrated and unhappy by the limitations to my lifestyle caused by COPD
21	I feel that I have good support from others like my family, friends, neighbours or carers	I feel that I don't have any support from others like friends, family, neighbours or carers
22	Overall I am satisfied with my life	Overall I am very dissatisfied with my life
26	I feel that I am in control of my condition	I feel that I don't have any control over my condition
28	I am happy to talk about the future	Talking about the future makes me feel depressed
32	I am confident in a 'flare up' I have quick access to treatment e.g. a rescue pack or access to my GP	I am worried that in a 'flare up' I don't have quick access to treatment e.g. a rescue pack or access to my GP
34	I am not worried about the care I will get from health professionals when I get a 'flare-up'	I worry about the care I will get from health professionals when I get a 'flare-up'

6.5.9. Overall fit to the Rasch model

Table 6.14
Overall Fit residual and Chi-square figures for remaining 10 items

Item	Fit Residual	Non-significant Chi-Square*
7	0.1	2.95
14	-0.98	1.86
17	-0.45	2.07
20	1.04	1.03
21	0.55	0.20
22	0.92	0.24
26	-0.39	4.9
28	-1.10	3.2
32	1.23	5.3
34	0.24	0.42
* (p value <0.01)		

6.5.10. Overall fit statistics in the Rasch model.

Following removal of the three items which were then deleted, a summary of fit statistics are shown in Table 6.14. At this 10-item stage the p value was non-significant, and therefore a Rasch model was achieved with 10 items. However, the aim was to develop an instrument with the minimal amount of patient burden, therefore using the Rasch model to develop the least amount of items possible. Despite, the overall fit of the 10 item solution the targeting of the item set was wide spread and therefore appeared suboptimal.

Therefore, further analysis was conducted to remove items in an attempt to improve the targeting (distribution). This then led to demonstrate and review the fit statistics for results of a ten, nine and eight itemed solution, which is presented further.

6.5.11. Ten item fit statistics

Table 6.15 give the over 10-item fit statistics followed by the person-item threshold distribution in figure 6.10.

Table 6.15
10-item fit statistics

Item Location		Person Location		Item Fit Residual		Person Fit Residual		Chi Square Interactions			PSI*	PSI**
M	SD	M	SD	M	SD	M	SD	Value	df	p		
0	0.2	-0.99	1.40	0.20	0.87	-0.52	2.38	22.2	20	0.33	0.77	0.77
M – Mean												
SD – Standard deviation												
PSI* - With extremes												
PSI** - No extremes												

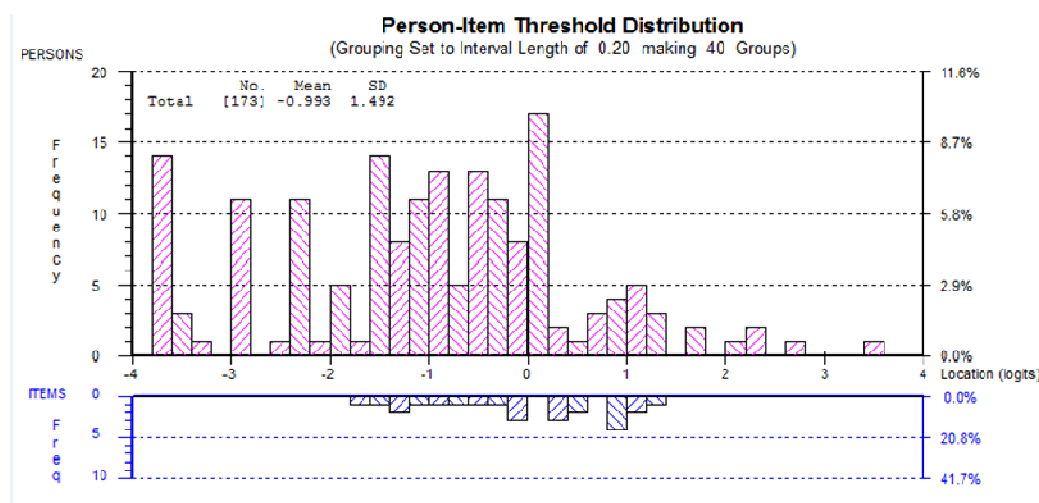


Figure 6.10 Person Item threshold distribution for 10 item fit

6.5.12. Nine item fit statistics

Table 6.16 give the over 9-item fit statistics followed by the person-item threshold distribution in figure 6.11.

Table 6.16
9-item fit statistics

Item Location		Person Location		Item Fit Residual		Person Fit Residual		Chi Square Interactions			PSI*	PSI**
M	SD	M	SD	M	SD	M	SD	Value	df	p		
0	0.1	-1.01	1.49	0.36	0.95	-0.47	2.10	14.2	18	0.71	0.75	0.71
M – Mean SD – Standard deviation PSI* - With extremes PSI** - No extremes												

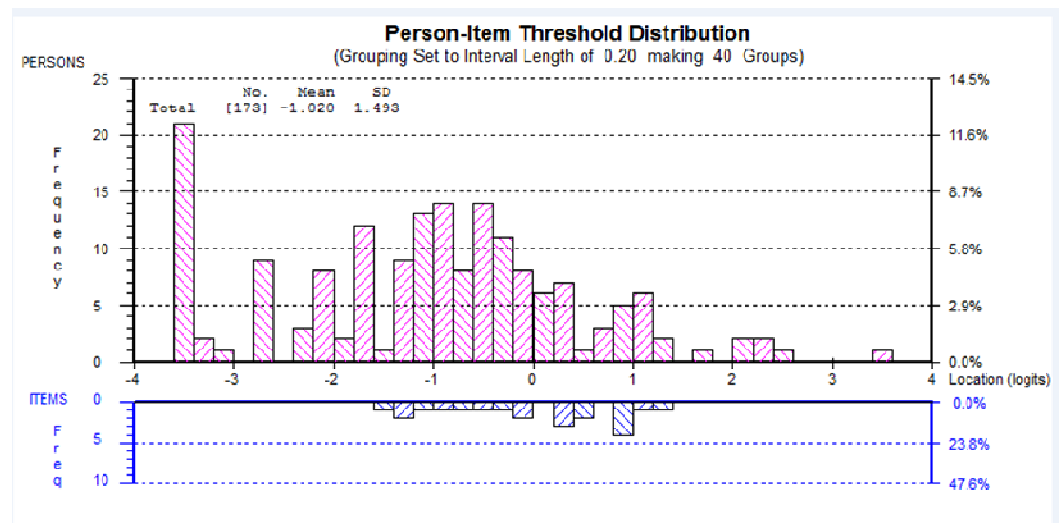


Figure 6.11 Person Item threshold distribution for 9-item fit

6.5.13. Eight item fit statistics

Table 6.17 give the over 8-item fit statistics followed by the person-item threshold distribution in figure 6.12.

Table 6.17
8-item fit statistics

Item Location		Person Location		Item Fit Residual		Person Fit Residual		Chi Square Interactions			PSI*	PSI**
M	SD	M	SD	M	SD	M	SD	Value	df	p		
0	0.11	-0.99	1.50	0.43	1.10	-0.51	2.38	17.3	16	0.36	0.75	0.73
M – Mean SD – Standard deviation PSI* - With extremes PSI** - No extremes												

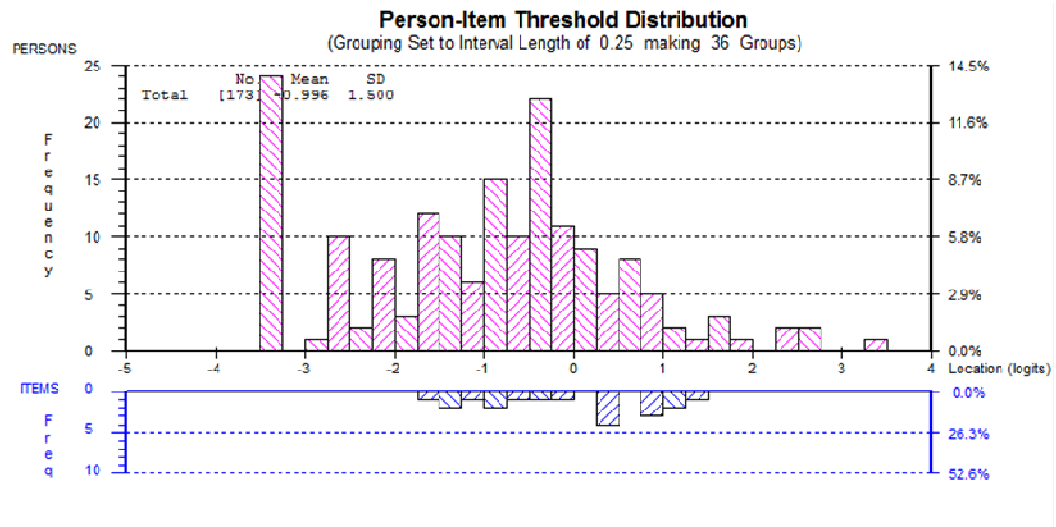


Figure 6.12 Person item threshold distribution for 8 item fit.

At an expert panel meeting consisting of nursing and medical academic professionals and healthcare professionals with an interest in COPD, the 3 models were presented. After discussion the 9-item solution was deemed to be the optimal solution for the final instrument because:

- It has a fit to the Rasch Model;
- The logit range was adequate between -0.134 -- 0.142;
- Better person item distribution (Figure 6.11);
- Expert panel felt item 22 would not add any additional value to the overall aim of the instrument.

Therefore item 22 ('Overall I am satisfied with my life'; 'Overall I am not satisfied with my life') was removed. This left a final 9-item instrument (Table 6.18).

Table 6.18
Final 9 items identified

Q	Low Scoring Question (0)*	High scoring Question (5)*
1	I am confident that my GP will listen to my point of view	I am concerned that my GP won't listen to my point of view
2	I have enough information about my condition	I am frustrated by my lack of information about my condition
3	I understand how my COPD treatments work	I am confused about how my COPD treatments work
4	I have accepted the limitations to my lifestyle caused by COPD	I am frustrated and unhappy by the limitations to my lifestyle caused by COPD
5	I feel that I have good support from others like my family, friends, neighbours or carers	I feel that I don't have any support from others like friends, family, neighbours or carers
6	I feel that I am in control of my condition	I feel that I don't have any control over my condition
7	I am happy to talk about the future	Talking about the future makes me feel depressed
8	I am confident in a 'flare up' I have quick access to treatment e.g. a rescue pack or access to my GP	I am worried that in a 'flare up' I don't have quick access to treatment e.g. a rescue pack or access to my GP
9	I am not worried about the care I will get from health professionals when I get a 'flare-up'	I worry about the care I will get from health professionals when I get a 'flare-up'

6.6. Reliability & Validity of the nine item instrument

6.6.1. Person Separation Index (PSI)

The Person Separation Index (PSI) for the 9 items was 0.71. This shows where the estimates are on the logit scale for each person. This result suggests that there is good person separation reliability.

6.6.2. Test-retest reliability

Test-retest reliability was evaluated via Intraclass Correlation Coefficients (ICCs) and was 0.78 for the 9 item instrument. This suggests that there was a good test-retest reliability.

6.6.3. Validity testing – correlation with PROMs

These were measured using an r value* and would only be significant, i.e. they are measuring the same construct as the COPD PREM, if they had a significant r value which was set at less than 0.01. The results were also plotted to show any possible correlation on a scatter gram (Table 6.19 and Figures 6.13, 6.14 & 6.15).

Table 6.19
Correlations: COPD PREM-9, CAT, Anxiety & Depression scale

	CAT Score*	Anxiety*	Depression*
Total 9	0.42	0.30	0.41
* r value = 0.01			

Scattergram Figure 6.13 (overleaf) shows there is a mild correlation with the total of the COPD PREM -9 and the total of the CAT score.

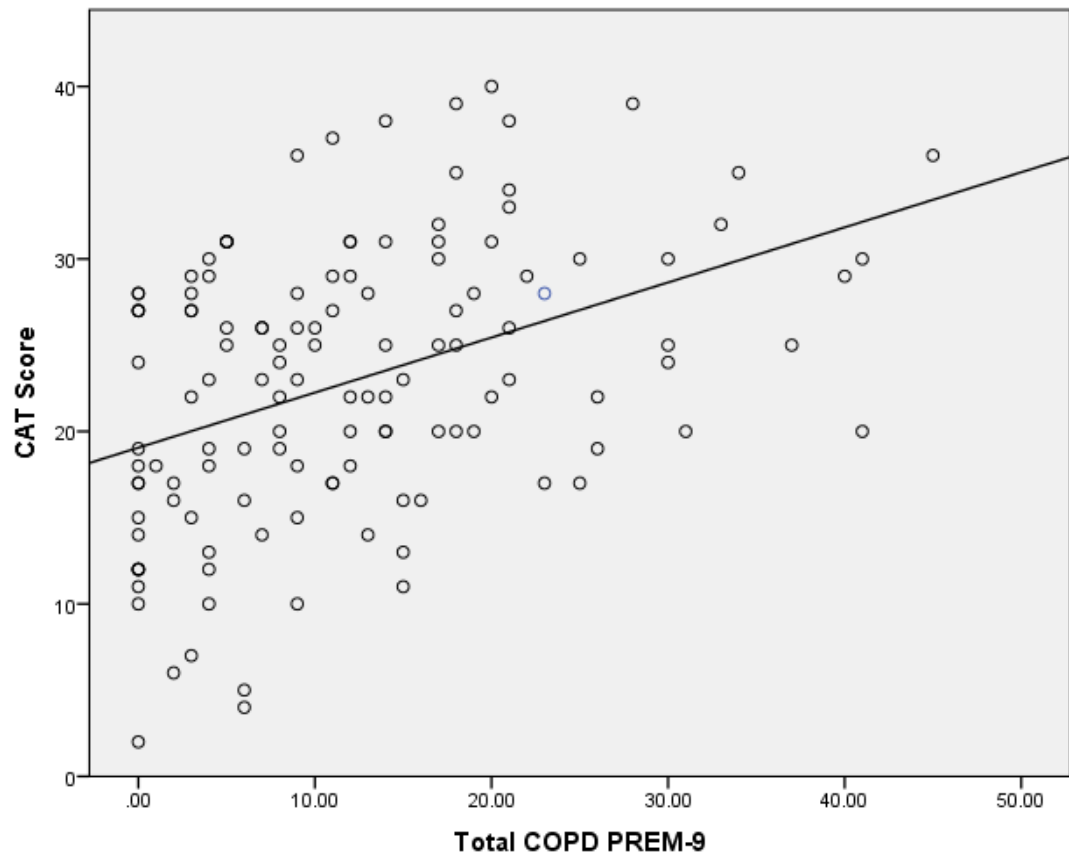


Figure 6.13 Scatter gram for total Scores of COPD PREM-9 & CAT

Figure 6.13 suggests that people living with COPD can have good and bad experience regardless of severity of COPD (the higher the CAT score the perception that the worse COPD). This is similar to the results of the total Anxiety and Depression scores association with the total for COPD PREM-9, as shown in Figures 6.14 and 6.15.

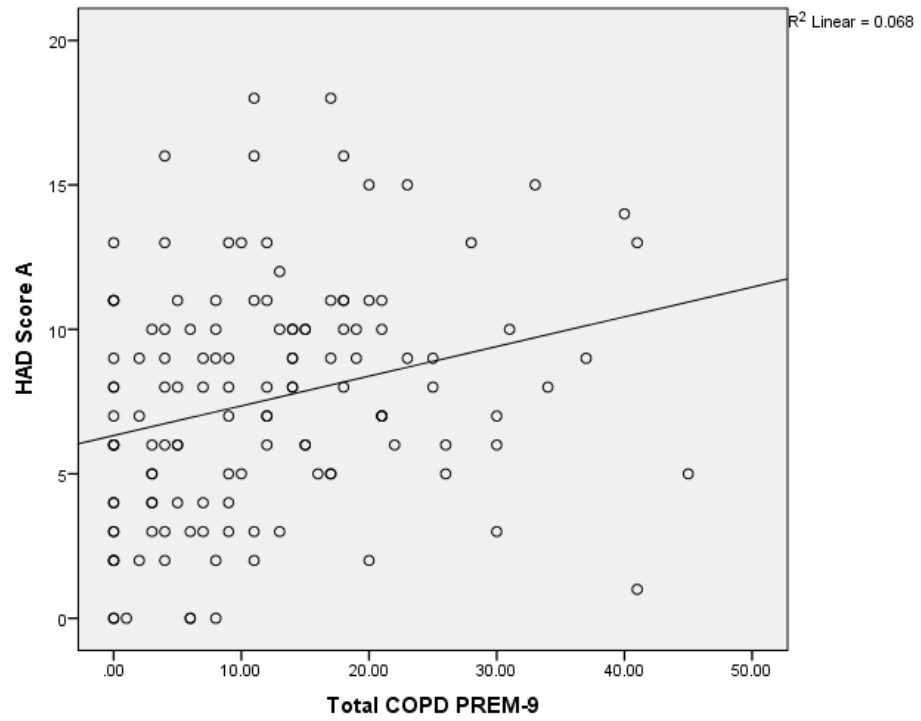


Figure 6.14 Scatter gram total COPD PREM-9 and Anxiety Scores

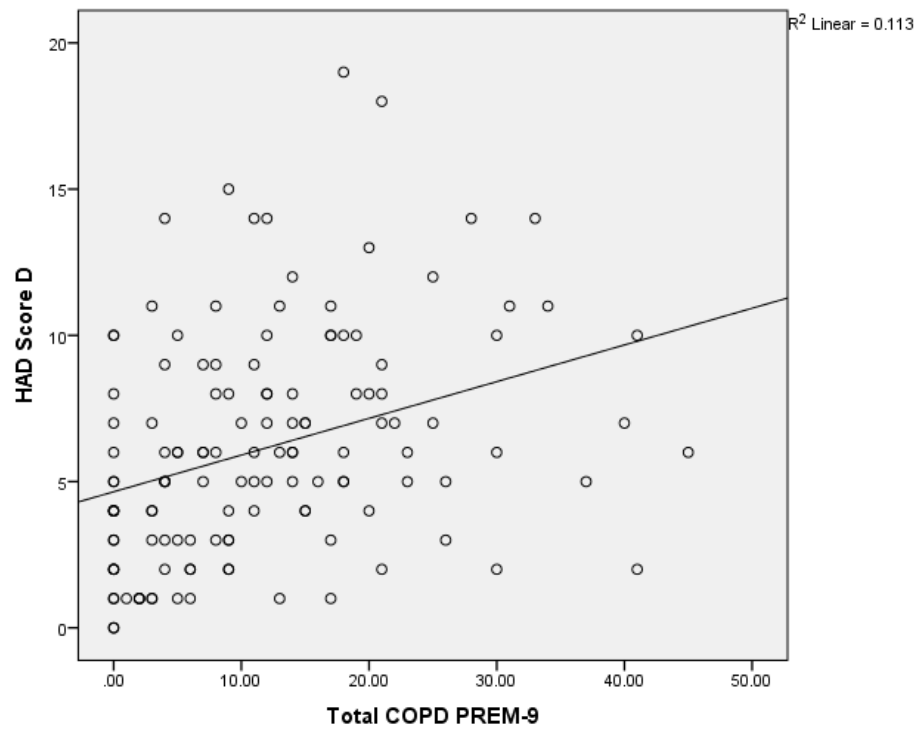


Figure 6.15 Scatter gram total COPD PREM-9 & Depression Score

6.7. Chapter Summary

This chapter has presented the results of the testing of the preliminary instrument in a cohort of 174 participants with a range of people living with COPD from across the country. The precise process of item reduction through the various techniques as demonstrated has reduced a 38 itemed instrument to a succinct 9-item instrument of which further discussion will take place in the remaining chapters.

CHAPTER SEVEN

CHAPTER SEVEN

7. Discussion

7.1. Introduction

The comprehensive overview of the results in Chapter Six detailed the overview population study and the subsequent scrutiny of the item reduction process. This thesis has produced a validated concise nine-itemed experience questionnaire using appropriate procedures to ensure that the items addressed issues of importance to people with COPD. The COPD PREM-9 covers a number of different aspects of COPD care divided into three main themes:

1. Everyday life with COPD;
2. COPD and usual care;
3. Exacerbation management in COPD.

These three themes identified are broad areas and have a variety of component items but address a number of specific topics in COPD, such as primary care relationships and self-management. The quality of fit of the COPD PREM-9 to the Rasch unidimensional model implies that the questionnaire has true interval scaling properties. This section will explore this thesis's findings and the COPD PREM-9 questionnaire in the context of contemporary research and national and international guidance and practice frameworks. The chapter will also demonstrate the associations between the items of the COPD PREM-9 against the Department of Health (2011) Patient Experience Framework. This framework introduced in the

literature review, gives eight overarching concepts recorded for a perceived positive patient experience.

7.2. The journey from thirty-two to nine items

7.2.1. Population & Demographics

In this thesis, a number of clinical variables were obtained at the time of recruitment. These included spirometry, MRC scores and smoking status. All participants recruited had a confirmed diagnosis of COPD, previously measured by lung function. Participants were recruited from a number of different NHS settings which included pulmonary rehabilitation, community COPD teams and hospital wards. Another group were recruited from the BLF Breathe Easy groups from across the country. These groups tend to meet monthly in a variety of locations from church halls to community halls and hospitals. This wide recruitment of potential participants has ensured that there is some variation between the baseline characteristics of the participants and between groups. All results discussed are of total participants unless specifically mentioned in reference to those participants recruited from hospital/community and those from the Breathe Easy (BE) groups. The overall severity of participants in this study showed a good representation of the general COPD population. There was a wider variation of severity of disease across the four different NICE (2010) classifications of participants with representation from mild to very severe disease. However, the mean FEV₁ for all participants was classified as moderate (FEV₁ 59%), with the mean (FEV₁ 48%) being severe in the Breathe Easy cohort. Due to the nature of data collection and the frailty of some of the participants recruited from the BE groups in particular, it is acknowledged that 17% (n=29)

of the spirometry data is missing from the overall baseline characteristics. But as there was already a good distribution of severities this is not detrimental to the study's overall aim.

The mean Medical Research Council (MRC) score was 3.4 (scale 1-5). This result also supports that a wide degree of distribution among the severity of COPD was recruited, with participants scoring 1 to 5 on the MRC scale, with 42% (n=73) of participants scoring an MRC of 4 or 5. This emphasises the fact that the population had a varied degree of breathlessness based upon the impact on an individual. There was no difference in MRC between those recruited from BE and hospital/community. Participants were mainly recruited from a diverse population across London Boroughs ensuring a broad representation of COPD patients. However, the study was not restricted just to London. There were also another five recruitment sites in England and the Channel Islands. However, written information and instructions were only available in English and therefore it is recognised that the study did not specifically target a number of groups of people in terms of ethnicity, people with learning disabilities and where English was not the participants' first language. Ethnicity was not recorded as part of this thesis but it must be acknowledged that due to the diversity of London there were a number of participants who represented the black and minority ethnic communities. Further testing is required within these groups including potential translation of the instrument.

There was no upper age limit set within the inclusion or exclusion criteria for the study, however all participants had to be over the age of 18. The mean age of the participants was 71 years which is not a dissimilar mean age to many of the previous studies identified in the literature review (Corcoran et al., 2013; Doos et

al., 2014; Rocker et al., 2013). The recent 2012/2013 National COPD Audit, also showed a mean age of 73 amongst the population who were included within the audit (British Thoracic Society, 2013). However, the NICE (2010) COPD guidelines suggest that COPD is suspected in those aged 35 years and older and therefore it was important that the distribution of age range was varied. The systematic and meta-analysis of the Global burden of COPD by Halbert et al., (2006, pp.526) emphasises the importance of age as a contributing factor to the growing prevalence of COPD, investigating studies with populations from < 40 years to ≥ 65 years with a diagnosis of COPD.

The participants, therefore, in this thesis, were aged from 42 to 91 years, demonstrating a extensive spread of age groups who completed the preliminary COPD-PREM. However, this variation in age may have been responsible for the identification of seven items associated with an age bias. The steady decline in lung function and its association with age is well documented (Gavin C Donaldson et al., 2005). It is also recognised by Ito & Barnes (2009 p.176) that it is not clear how the aging process is involved in the decline of lung function and inflammation in COPD. Donaldson (2002 p.842) however, argues that the number and frequency of acute exacerbations of COPD can contribute to a long-term decline in lung function in people with moderate to severe COPD. Age, therefore, cannot be seen in isolation to understand whether people have a good or bad experience of living with COPD, as other contributing factors such as exacerbations and the rate of decline in lung function also contribute to the burden of symptoms. The Fletcher et al. (2011 p.2) international survey of the working population (age 45-67 years) argues that COPD also has a 'significant personal, economic and societal burden on the working age people'.

In this thesis the item reduction process for linking individual items and testing for associations with age was the Spearman's Correlation, which resulted in six items being removed. These items which were deleted through this process were associated with different aspects of COPD care, from scared of getting a cold to the understanding of the condition and management of fear. There was a direction with these responses towards a positive experience (low score) in the older age groups, thus suggesting that within the six items deleted they were correlated towards the specific older age group and not the severity of COPD. On reviewing the six items, all apart from one item did not mention COPD or was linked to a symptom associated to the disease. Thus, the items were very generic in nature and could potentially be applied to any condition. It is important to note that 90% of the sample group were over the age of 60 years potentially contributing to the number of age bias results. Other respiratory instruments in their development designs (Yorke et al., 2012) have also deleted items due to age bias thus this thesis is not isolated in this area.

The gender of participants may have also introduced bias to the PREM development. While no attempt was made throughout the recruitment process to collect equal numbers of male and female participants, an even distribution was achieved with 52% (n=91) of the sample being female. There was a slight mismatch in the two different groups with an increase in females, 57% (n=50) recruited from the BE groups. However, as previously mentioned, all results were investigated as a total population. This even distribution allowed for gender bias to be analysed using the hierarchical method and the use of the Mann-Whitney-U test. The even distribution may have contributed to the fact that only one item was deleted at this stage which was item 35 I am not scared of getting a cold or an

infection (low score item answer). This item had already been deleted in the age bias process. The descriptor 'scared' used to describe the experience of getting a cold or infection was not a descriptor word used in the rigorous literature review in other studies on experience, but was a predominate description of colds and infections identified in the initial qualitative study. The concept of an infection was also used in other items in the instrument (items 32, 37, 38) to describe infection but terminology was changed and the instrument used 'flare-up' as another descriptor of infection. It may suggest that people relate infection to other ailments and not colds. COPD patients use terms such as flare up which are more commonly used to describe this in COPD (Osthoff & Leuppi, 2010).

The two systematic reviews of patient experience by Disler et al., (2014); & Giacomini et al., (2012) did not attempt to highlight whether there was a real distinction in the experiences and descriptors used for age or gender to describe their experience. COPD however, has been traditionally been seen as an 'old man's disease', associated with higher incidences of smoking among men. This perception is changing with smoking rates for women increasing now overtaking men in some countries (Watson et al., 2004). In a large cross sectional study questionnaire based study of 65,717 of cigarette smokers in Norway by Langhammer et al., (2000, p.917) stressed that women report much more respiratory symptoms than men. Cigarette smoking is the number one cause of COPD globally. Gender differences in COPD are widely reported and the Aryal et al., (2013) review and update on smoking concludes that a number of differences exist between men and women living with COPD. A number of studies reviewed by Aryal et al., (2013, p.212) relate to the clinical presentation of the disease. For example, women had higher levels of anxiety and depression and also self-

reported dyspnoea was higher in females. His review also advocates a number of other gender differences in the diagnosis, treatment options and epidemiology in COPD care. There is no indication of the measurement of gender difference in the experience of living with COPD. But a great understanding of the effects of COPD on both age and gender in the physical, functional, social and psychological affects have been well reported by a number of qualitative and mixed method approaches (Skumlien, Haave, Morland, Bjørtuft, & Ryg, 2006; Tsiligianni, Kocks, Tzanakis, Siafakas, & van der Molen, 2011).

7.2.2. Hierarchical methods of item reduction

As previously stated the process of item reduction through hierarchal methods ensures internal validity (rigor and the removal of bias) and external validity (the ability to generalise) among the initial proposed items. To ensure consistency across all items, six were deleted as part of the hierarchical methods where more than 15% of participants had failed to complete them. Two of the items (10 and 11) were concerned with the experience of undertaking pulmonary rehabilitation. PR is a significant non-pharmacological approach to the management and care of COPD (Ries et al., 2007), and experience in this is critical to capture. But as part of the wider programme of COPD work a PREM in PR was also being considered and this thesis will also inform the direction of this future work. Additionally, PR is not undertaken by every COPD patient who may complete the COPD-PREM. Therefore the deletion of these items reduced the confusion that may lie with completing the questionnaire and added value by making the instrument more generic in its field. This is possibly the reason why there was a high level of missing responses for these two specific items, if participants were unaware of what PR was. This is similar to two further items (3 and 4) which asked about the

experience of smoking history. Item 3, I have given up smoking and I am 'confident that I will not start' and item 4, I want to stop smoking and I believe I can – lower score answers – had a large missing value at 76% (n=132).

This is further supported in that 72% (n=125) of the participants completing the questionnaire were self-reported as being ex-smokers, and 12% (n=20) as non-smokers. Smoking cessation, like PR, is a major part of COPD care, but it is clear that many people choose not to answer these items. Giacomini et al. (2012) identified two conflicting accounts to the recording of smoking. Firstly, the belief that smokers were diagnosed with COPD for other reasons than accepting smoking was the cause. And patients who expressed 'blame' and 'regret' for knowing that smoking did cause COPD. A longitudinal and descriptive study investigating the experiences of self-blame and stigmatisation for self-infliction among individuals living with COPD by Halding et al., (2011, p.100) affirms these accounts clarifying that patients often felt 'disgraced' with a heavy burden of self-stigmatisation. But it is also claimed that there is a lack of support from healthcare professionals which may not be localised to the COPD population (Jenerette & Brewer, 2010). In an editorial review on the patients validation of self-reported smoking by Rebagliato, (2002 , p.163) concludes it is also acknowledged that self-reporting can be unreliable if the participant is under pressure because of social or medical disapproval. However, Soulakova et al., (2012, p.952), reporting on a large cohort study on the reliability of adult self-reported smoking history, argues that their findings suggest that 'self-reported smoking history characteristics can be reliable'. The high proportion of ex-smokers in this cohort is a positive finding but must be taken on the backdrop of differing option and

evidence. The high level of missing data for these two smoking items supports this.

The overall aim of the questionnaire was to explore the experience of living with COPD, or of healthcare. Having deleted these two smoking-related items similar to PR items the proposed questionnaire feels more patient-centred and COPD generic, but remaining disease specific in its measurement. Another item that was deleted because it had missing data of 17% was item five: It was a relief to have a diagnosis for my symptoms. This item caused a great deal of discussion among the participants and was the item that most frequently needed explaining (which in itself suggests the item is not worded clearly enough to be worthy of inclusion). However, within the literature the notion of the 'diagnosis' of COPD was a key theme in Study One (COPD PREM development), and was supported by McDonald et al., (2013, p.28) who stipulate that many of the participants from their study were 'frustrated' or 'disconcerted' about not having a diagnosis for symptoms. But, a number of participants completing the preliminary COPD-PREM also made similar references to this, comments such as 'it was such a long time ago I can't recall if it was or not [a relief]'; 'of course it wasn't a relief, I had just been diagnosed with COPD, and I just thought it was down to my age' and 'who knows?' The diagnosis of COPD is an important part of the patient's journey. The experience however, of this 'diagnostic phase' shows wide variation from mis-diagnosis to living years with symptoms before a diagnosis is finally made. Both examples impact greatly on the patient supported by the literature review (Disler et al., 2014).

Therefore, to measure the experience of the diagnosis in a PREM questionnaire proved difficult. This may be due to the terminology used or the length of time

it takes from symptoms to diagnosis. The study by Lindgren et al., (2014, pp.441-442) on the experience of the diagnostic phase of COPD highlights that diagnosis of COPD is a complex and a life-changing event where patients are dealing with many new terms such 'chronic' and 'self-inflicted'. COPD is not isolated in this. A phenomenological study to look at the lived experience of people with Multiple Sclerosis (MS) by Lowden et al., (2014, p.E14) stressed 'acknowledging the illness as part of oneself' was a key theme from the research and that was clearly denied in another long-term condition, advocating that the experiences of other long-term conditions follow similar avenues.

Communication with healthcare professionals is an important aspect in the long term understanding of the relationships between the different groups of healthcare professionals (HCPs) and the patients, which this instrument does not address specifically. Lindgren et al., (2014, p 443) makes the suggestion that there are two main areas of communication at the diagnosis phase: that of 'negotiation' and that of 'acceptance and new understanding. Reflecting on the comments made when participants were discussing the item, it is feared that many were still in the 'negotiation phase', making it harder to answer the item.

The final item which was deleted due to missing responses was item 15, 'I understand about my COPD tablets'. This item also caused a lot of discussion with healthcare professionals and participants as a high number of participants involved in the study were not on oral medications for their COPD, but were on a number of other oral medications for other conditions. Some were unclear if they were on 'tablets' for their COPD or not. Therefore, it was not answered in 28% of participants, and a high number scored it a 0 (the lower score number, but good experience) I suspect as they were unclear. Unlike inhaled devices, people who

are taking oral medications for their COPD tend to be in the very severe classification. A number of patients with COPD also had experienced exacerbations of their COPD caused by infection, with a need to introduce rescue medication which is recommended by NICE (2010). Additional oral medication is taken in tablet form as well as continuing inhalers. The debate about whether this was included as 'COPD tablets' caused a lot of discussion, especially in the different Breathe Easy groups, and it was not isolated to one group. Therefore the deletion of the item enabled the final PREM-COPD items to focus on more concise items which were understood across a larger group of COPD patients.

The hierarchical methods continued to test for the floor and ceiling effects of an item. This entailed setting a 'cut-off' level for item selection, in this case more than 40% of patients, as a total group, responded a 'zero' (floor effect). Of the twelve items deleted due to the floor effect was an item had already been deleted (item 11 on PR). All items which were deleted were items which were all devised from the themes identified in Study One (COPD PREM development) and based and supported within the literature review on the concerns with usual care in COPD and living with COPD. In particular, item 25 'I am not embarrassed to tell others about my condition' (good experience answer), had a 59% 'zero' response rate. This suggests that over half of the total participants were not embarrassed by their condition. 'Embarrassed' is not a descriptive word used within the Giacomini et al., (2012) or Disler et al., (2014) reviews to describe similar experiences, other similar items seeking experience on daily life and COPD included items 27, 28, 29 and 31 which explored areas such end of life (a similar question was retained) and 'I enjoy my life'. The remaining items deleted all had connections to medication

management (items 17 & 19). A further two items had already been deleted in other areas of the item reduction process.

There were a further two other items (8 and 13) which had a floor effect and were deleted. These were also included in the item-to-item correlations. The two items were exploring the experience of healthcare workers, item 8 being 'I am very pleased with health care workers' (low score answer) and item 13 'The information I have been given is consistent' (low score answer). The hierarchical methods reduction showed a positive r value (>0.80) suggesting there was an internal correlation to each other and item 11 on PR which had now been deleted. The reasons for this are open for discussion, but there is a strong link between pulmonary rehabilitation and an increase in improved information need in condition specific learning for the disease, alongside an increased activity and improvement in quality of life (Ko et al., 2011). Together staff anecdotally also receive high praise and patients experiences are generally overall positive. However, the Royal College of Physicians (RCP), in partnership with the British Thoracic Society, is working to undertake PREM-specific research in pulmonary rehabilitation, as little is known nationally about the experiences of patients undertaking this exercise. It is hoped that this work will also influence some of the thinking related to partnership with them. However, a systematic review by de Sousa Pinto et al., (2013), specifically researching COPD patient experiences with pulmonary rehabilitation, only identified eight studies, but did support earlier thinking that PR empowers patients through health education, including specific aspects of the COPD journey. There were no items that achieved a ceiling affect. It is unclear why such a high number of items reached a ceiling affect. Some discussion on these items was apparent on the internal discussion that happened in the Breathe

Easy Groups and individually over the meaning of items. But to ensure consistency and increase the appropriateness of the PREM COPD instrument items, need to be deleted to ensure maximum reliability and validity.

Therefore, in summary, there were a total of twenty-two items deleted (Table 6.9) as part of the hierarchical methods of item reduction taking into account the demographics including severity of lung disease, age and gender. Having discussed the items that were removed it is evident that appropriate items were deleted to develop a more patient-centred instrument to be used with the whole COPD population, reducing bias against age or discriminating against smokers or whether a person had undertaken pulmonary rehabilitation or not. Focusing on reducing items also ensures consistency and increases relevance to the aim of the study (O'Leary & Jones, 1998).

7.2.3. Face Validity

The remaining sixteen items were then discussed within a respiratory expert panel to develop face-to-face validity. Each item was assessed individually. Initially, none of the data was shown and then subsequently each item was scrutinised including the data from the item reduction hierarchical process, as well as reviewing the aims and objectives of this study. Participants' comments were also noted for each item and were shared among the group. In the first round of face-to-face validity, item 1 was removed ('I am not shocked by my COPD diagnosis'). This decision was made on the basis of comments similar to that of item 5 regarding the relief for having a diagnosis. The descriptive word 'shocked' confused some participants, many suggesting it was such a long time ago they were now not sure how they felt at that time. Also this descriptor was not identified

in either of the systematic reviews by Giacomini et al., (2012) or Disler et al., (2014) or the quantitative paper specifically exploring the experiences of the diagnostic process of COPD. Descriptors such as 'negotiation', 'past' and 'challenge' were used (Lindgren et al., 2014).

There were a further two items (37 and 38) that were also deleted following a second round of face-to-face validity. These two items were associated with exacerbations of COPD. Two of the respiratory experts suggested that they did not add 'value' to the additional items in the measurement of experience. It was agreed that both items were related to 'symptoms' associated with exacerbations of COPD rather than experience. Both items also had a poor severity distribution which could give a potential bias. Sleep is an important aspect of COPD care, however it is recognised by Eckerblad et al., (2014) as an associated high symptom burden when assessed using a multidimensional symptom profile, with patients with stable COPD. However, this is contrary to the Giacomini et al., (2012) review which argued that patients were more frightened about not waking from sleep due to symptoms. After further discussion within the expert group and further review of the distribution of the severity of COPD, given these two different opinions it was agreed that both items 37 and 38 would be deleted leaving a total of 13 items to be included in the final Rasch analysis.

7.2.4. Rasch Analysis

The reduction process of the remaining 13 items followed a rigorous methodology when entered into the Rasch model. The items that were of poor fit or poor measurement properties were deleted following the intricate process outlined in Chapters Six and Seven. The three items deleted following the Rasch analysis

went through this process and supports the proposal by Jones et al. (2009, p.652) that

when deciding whether to include or exclude an item during questionnaire development, it is necessary to balance its weaknesses and strengths against its overall contribution.

Therefore not only were the three items (16, 9 and 2) deleted because they did not fit the unidimensional Rasch model. But also examined in there context and overall expert scrutiny of whether the items that remained were broad enough to cover the initial aim of the study. Item 16, 'I am confused about how my inhalers work' (high scoring answer) was deleted as it did not fit the Rasch Model and had a high fit residual and thus there was an overt discrimination between the interval class groups within this item (16). The Rasch model suggested that, overall, participants had a higher-than-expected 'bad experience' and a higher-than-expected 'good experience' than the model predicted using the three class interval groups along the continuum as diagrammatically shown in Table 6.12 (Chapter Six, p.169).

The three items which were deleted in Rasch were also reviewed by the expert group. There was concern that item 16 which related to 'medicine management' and the use of inhalers would be a 'good' item to use because of wide-spread literature on inhalers (Molimard et al., 2003). It is common knowledge among the respiratory community that patients and healthcare professionals have poor inhaler technique. A cross-sectional study of GP practices in the Netherlands undertaken by Hesselink et al., (2001, pp.255-256) identified that over 24% of patients made one critical mistake in using their inhaler. This was similar to other studies, some with a much higher percentage making mistakes such as Hämmerlein et al., (2011, p.61) reporting 78.9% of patients with poor technique.

When considering the aim of the thesis and the evidence behind inhaler technique, the inclusion of this item could potentially have been useful. If a patient scored a zero (good experience) potential for modifications of inhaler technique could be missed. The checking of inhalers, however, should be a routine part of COPD care and is outlined both in the Quality Outcome Framework for general practice as well as a recognised part of the COPD assessment recommended by NICE (2010).

The two further deleted items, item 2 'I have come to terms with my diagnosis of COPD' (low score answer), and item 1, regarding 'being shocked' about the diagnosis of COPD were very similar. From participant feedback regarding this item a number of participants had expressed that they continued not come to terms with the diagnosis, but did not want to score a higher value (denoting a worse experience) as even though they hadn't accepted the diagnosis of COPD, it wasn't affecting their everyday life or experience of living with the disease. However, coming to terms with a diagnosis is an important aspect of the patients pathway, as previously discussed in the literature (Disler et al., 2012; Giacomini et al., 2012). The Lindgren et al., (2014, p446-447) study also stressed earlier that descriptors such as 'struggle' and 'honesty' must also be considered at diagnosis. However, this item did not fit the Rasch model and to ensure an appropriate fit to Rasch and reflecting on the previous statement by Jones et al., (2009), on finding the 'right balance' in the instrument, this item was deleted. Though diagnosis remains a key feature of COPD care, there are conflicts over reported concerns in the literature and with the findings of the previous qualitative study (Study One) and how participants report their findings in completing an instrument. This is an important finding and will be reported back to the COPD group. As all items relating to the diagnosis of COPD were now deleted from the original COPD

PREM-38 through item reduction. The four themes previously identified in Study One (COPD PREM development p.126) would now be reduced to three themes, again allowing for a more concise instrument in its final stages.

The final item to be deleted was item 9 ('I am happy with the length of time to see GP') (lower scored answer). The GP is a key orchestrator of care and the literature primarily focuses on the relationship and experiences with patients' GP consultation rather than the time it takes to get an appointment (Powell et al. 2013; McDonald et al., 2013). The descriptors describe 'communication' and 'understanding' as important words used to describe this experience. This item was also deemed more 'patient satisfaction', if we reflect on the definitions of this rather than capturing the experience of the relationship between the patient and the GP as discussed as an important concept in the literature review.

As the results suggest, after these three items were deleted there was a subsequent fit to the Rasch model with a non-significant p value. The expert group, consisting of the initial reference group plus additional academic staff who were familiar with the Rasch process and familiar with scales and instrument development, as well as representation from the British Lung Foundation, reviewed the remaining items and, after discussion about the overall construct of the questionnaire and the data in relation to the overall distribution of the items and their logic value, there was an agreement to delete item 22 ('Overall I am satisfied with my life' (low score answer). It was agreed that the terminology used to describe the item was not in relationship with the experience of living with the disease. This is supported by the literature; neither Giacomini et al., (2012) or Disler et al., (2014) use the descriptor 'satisfied' to describe any aspect of care

documented in the systematic reviews. The deletion of this item now left this a final 9 items, from now on called the COPD-PREM-9 (Figure 7.1).

Internal consistency was used to estimate homogeneity of the items of the COPD PREM-9; that is the extent to which the nine items generally measure the same construct. This was assessed by analysis of the Person Separation Index (PSI). An acceptable PSI score of 0.71 was found. This is indicative of the new instrument's internal consistency for the population studied. Though these results suggest that there is good person separation reliability, it was recommended in the methods that a PSI of 0.85 (Tennant & Conaghan, 2007) was needed for individual use. Expert advice on the Rasch analysis was therefore sought and a member of the expert respiratory panel was asked to provide this. Discussion suggested that the PSI for reliability for this cohort and development of the final PREM COPD-9 was of a good level and thus is reported as such.

Stability of the COPD PREM-9 was then assessed over seven days. Extended delays for questionnaire returns were minimised as much as possible and those returned after the seven days from the initial return date were not included in this aspect. 50% (n=87) of participants returned Pack B of which just over half (56%) were from the Breath Easy groups so there was a good distribution of participants from all areas. This was a much higher return rate than was suggested of 20% (Jones et al., 1999). A systematic review of postal returns by Edwards, (2002, p.23) concludes that a lack of return of questionnaires can potentially add bias and reduce validity to a study. When testing the stability of a questionnaire, it is important to compare like with like. In relation to the underlying construct being measured by the questionnaire, participants' health status needs to be relatively constant over the time period of assessment. To assess stability of participants'

health status, participants completed a global health change score at follow-up. Correlations between the COPD PREM-9 and between baseline and follow-up were examined for those who reported that their global health was 'the same'. The ICC for the COPD PREM-9 was high, indicating that the scale was stable at the time. Given that the time period between completing the questionnaires was seven days, the observed stability is more than likely a true reflection of stability rather than participants repeating and remembering responses to the initial COPD PREM questionnaire (Yorke et al., 2012a).

7.3. The COPD PREM-9

The final content of the COPD PREM-9 covers three main areas in COPD, using a wide-ranging scale from zero (good experience) to five (bad experience) making it concise to administer and easy to use as a patient. The first section is on 'everyday life with COPD', concerned with four questions covering aspects that are specifically patient-centred, and drawing upon current patients' experience of living with the disease and including questions on support and guidance on living with the disease. The second three questions relate to the experience of 'everyday care in COPD and are constructed on primary care and information and understanding of the disease. And, finally, a third section has two further questions on self-management of exacerbations of COPD.

COPD Patient Experience Healthcare Questionnaire



This questionnaire is designed to help us learn more about your experience of living with Chronic Obstructive Pulmonary Disease (COPD) and the care that you receive in relation to this condition. Please read the questions carefully and ask if you do not understand anything. For each question please add a cross to one box that best matches your experience. (Score: 0 Low – 5 High).

EXAMPLE:

LOW SCORE		HIGH SCORE
I am very happy	0 1 2 3 4 5	I am very sad

Usual care in COPD - These questions relate to the everyday usual care given of your COPD

LOW SCORE		HIGH SCORE
1. I am confident that my GP will listen to my point of view	0 1 2 3 4 5	I am concerned that my GP will not listen to my point of view
2. I have enough information about my condition	0 1 2 3 4 5	I am frustrated by my lack of information about my condition
3. I understand how my COPD treatments work	0 1 2 3 4 5	I am confused about how my COPD treatments work

My everyday life with COPD - These questions relate to your everyday life with COPD

LOW SCORE		HIGH SCORE
4. I have accepted the limitations to my lifestyle caused by COPD	0 1 2 3 4 5	I am frustrated and unhappy by the limitations to my lifestyle caused by COPD
5. I feel that I have good support from others like my family/friends/carers	0 1 2 3 4 5	I feel that I do not have any support from others like my family/friends/carers
6. I feel that I am in control of my condition	0 1 2 3 4 5	I feel that I do not have any control over my condition
7. I am happy to talk about the future	0 1 2 3 4 5	Talking about the future makes me feel depressed

COPD Exacerbation (Flare up) - These questions relate to a flare-up of your COPD

LOW SCORE		HIGH SCORE
8. I am confident that in a 'flare up' I have quick access to treatment like a rescue pack or access to my GP/nurse	0 1 2 3 4 5	I am worried that in a 'flare up' I do not have quick access to treatment like a rescue pack or access to my GP/nurse
9. I am not worried about the care I will get from health professionals when I get a 'flare-up'	0 1 2 3 4 5	I am worried about the care I will get from health professionals when I get a 'flare-up'

Figure 7.1 Final COPD PREM-9 Instrument

Set within the national guidance of NICE (2010) and The Department of Health and NHS England context, and reported within this thesis the heightened importance of measuring experience is fast becoming a fundamental aspect of daily healthcare. Therefore, it was imperative that any generation of new experience instruments or measures must fulfil all or part of the Department of Health (2011) NHS Patient Experience Framework as used as the framework underpinning this study. The framework approved by the NHS National Quality

Board (NQB) has a working definition of patient experience to enable and guide the clinicians and managers in the measurement of patient experience across the NHS. This framework, as previously mentioned within the literature review, outlines the eight key concepts which are critical to the patients' experience or journey through NHS Services (Department of Health 2011). Thus, a correlation of the COPD PREM-9 and the framework was undertaken to establish whether any appropriate links and associations are made between the underpinning experience framework and the items generated for the new COPD PREM-9 instrument.

As previously mentioned the COPD PREM-9 was finalised into three groups: my everyday life with COPD; usual care in COPD, and; COPD exacerbations. It was clear there is a correlation or association across all of the eight concepts of the NHS patient experience highlighted within the framework and the 9 items generated in the final PREM questionnaire. This adds value and professional rigor to the newly created instrument demonstrating that the values of experience as shown in the framework such as person-centred, communication, involvement of family and friends and access to care are being addressed in the items generated within the new PREM-COPD-9. The robust process in the development of a new

instrument by patients for patients is a critical focus in this development, as the experience framework was developed by patients for patients. To illustrate these points further and demonstrate this association between the COPD PREM-9 and the Department of Health (2012) Patient Experience Framework the three themes will be discussed as well as further discussion on the current literature.

7.3.1. My everyday life with COPD

The four items that are included within this section are connected to the everyday life of living with COPD and include questions relating to the limitations (item 4) on lifestyle and whether participants had accepted them or were frustrated by them. Both the Disler et al., (2014) and Giacomini et al., (2012) systematic reviews identified 'frustration' as a common descriptor of lifestyle and the impact that COPD had on daily life was a theme throughout the literature. Talking about the future (item 7) and control (item 6) were also themes as previously identified in the literature review and reported by Lindgren et al. (2014). The association of 'everyday life' with the 'NHS Patient Experience Framework' highlighted a number of concepts in this framework, firstly, the concept of 'welcoming the involvement of family and friends', though the literature review only touches on this area. The impact of carers and family is an important factor with many carers feeling 'helpless' and 'afraid' as evidenced in the systematic reviews by Giacomini et al. 2012. And this question is identified by item 5. Understanding whether support is provided by family and friends is an important aspect to managing long term care. If patients feel unsupported or have no support (bad experience), this would promote the healthcare professional to identify future help or guidance and ensure carers and family are involved and maintain support for all parties in future care.

A exploratory, descriptive design study by Caress, Luker, & Chalmers, (2010, pp.571-572) explored both the 'patients and carers' views on promoting the health of COPD. This example and their findings emphasise the point that healthcare professionals need to maximise the benefits of health promotion to patients and families, to maintain healthier lifestyles. This is one good approach in which patients and family can work together to improve health and the experience of living with the disease.

The experience of emotional support and impact of disease items 4-7 address this issue exploring the earlier discussion on control and limitations in COPD. Addressing these issues of experience and enabling and opening up discussion between the healthcare professional and patient, on issues such as anxiety and depression, are critical to diagnose and treated to ensure the positive experience and improve quality of life of people living with the disease. Information, communication, and education are all critical to every patient, and are highlighted as one of the eight concepts in the framework. One of the key aspects of this is the association with health promotion but also prognosis. The evidence in the Disler et al., (2014) and Giacomini et al., (2012) reviews make it clear that discussions on prognosis and end of life care is sparse. One of the reported challenges in this is that healthcare professionals feel unprepared or unable to approach end of life discussions. Crawford, (2010, p.1164) affirms that 'there is little evidence that open discussions regarding end-of-life decision-making are taking place routinely'. Item 7 of the questionnaire identifies this issue using 'the future', rather than end of life or medical terminology such as prognosis. Item 7 'I am happy to talk about the future' (low scoring answer) gives potential in two ways, firstly it enables the patient to take control over the decision on their current

experience of 'the future' and secondly allowing the healthcare professional to feel empowered to explore this item further over time with patients, potentially opening up conversations about the future. From the discussions that were had in the Breathe Easy groups it was very much seen as a 'positive' question. This approach is maintained by MacPherson et al., (2011, p.1) whose qualitative research on interviewing patients nearing end of life suggests

improved information provision could improve relationships between patients and healthcare professionals, as well as enabling patients to be more involved in current decisions about their care

The underlying principles of patient experience are concerned with improving quality of care to patients. If the development of this PREM can help start these important discussions then the quality and patient-centred aim of the COPD PREM-9 is achieved.

Current clinical status such as symptoms are measured in other health related quality of life scores such as the CAT. Other areas such as fatigue, control and limitations are essential components to the COPD PREM-9. This approach deviates from the measuring the traditional experience of the impact of symptoms and on quality of life, shifting this approach towards the measurement of the experience of living with COPD and generating an holistic understanding of this experience, whether certain aspects are good or bad along a scale measure, translating to whether there is a move towards a good experience of shift towards a poor one.

7.3.2. Usual care in COPD

The three items under this heading were related to usual care given to patients with COPD and are supported by the literature (Disler et al., 2014; Giacomini et al., 2012) in terms of the aspects of experience which they are measuring. This section of the questionnaire links a number of the concepts of the NHS Experience Framework together: 'access to care and the care setting' to a concept of 'information, communication and education' which fit well with item 2 & 3 on the information and understanding of COPD and its treatment.

It was evident in the literature review that the GP was the key healthcare professional that patients wanted to be involved in their care and is usually the first 'port of call' in times of exacerbation or 'need' (Powell et al., 2013). Item 1 clearly supports this experience of GP engagement looking at the positive and negative experience of whether the 'GP will listen or would not listen to the concerns'. Disler et al., (2014, p.5) reported that many patients had poor experience in terms of communication with their GP which included themes such as diagnosis, treatments and current symptoms. This item is critical item as Powell et al. also suggest through their focus groups with patients that the GP should be the 'gate keeper' of care in the community. So patients need to ensure a positive experience and feel listened to. This item, like all items, will also support the healthcare professional understand concerns and help open up discussion around them or if used in the GP practice help the GP understand the patients' experience further.

The further two items concerned with information and understanding COPD use the descriptors that were most commonly reported in the literature and by COPD patients. The descriptors 'confused' and 'frustrated' were key words which

participants related most whilst undertaking the study, with several comments reporting 'confused' 'yes that's exactly how I feel'. These two items allow for discussion with the patient on the level of understanding and information needs often not addressed together. There are potentially a number of strategies which could be used to improve experience in these two areas. This section and the items identified are strengthened by the support of the literature and the underlying concepts within the NHS experience framework.

7.3.3. COPD Exacerbations

The two last remaining items relate to exacerbations of COPD and access to healthcare professional support and treatments (item 8) as well as to the care related to this (item 9). The Literature Review supported the need for the inclusion of exacerbations in the PREM. This was an important aspect as the Literature Review and subsequent supporting literature (Arostegui et al., (2014) and supported by Steele et al., (2009) suggests exacerbations are a frequent occurrence in patients with COPD, of which the need for healthcare intervention is great (NICE 2010). However, the experience of exacerbations and their management is varied. The descriptor 'worried' was used in many different aspects of COPD experience including diagnosis and end of life care and it was a descriptive word used and supported by the Literature Review (Giacomini et al., 2012) in exacerbations. Worried, was also well documented and one of the descriptive words used within Study One (COPD PREM development). The correlation of both items to the NHS experience framework are associated to the concepts of 'emotional support' and 'access to care'.

Ensuring that COPD patients have quick access to appropriate support and to medical advice in time of an exacerbation is critical (Arostegui et al., 2014). The benefits of 'rescue medications' in an acute exacerbation continues to be highlighted. The impact of implementing self management plans and rescue medications across three hospitals by Khachi et al., (2012, p.2903) made recommendations that this access to rescue medication reduces re-admission into hospital (5.7%). Therefore understanding the experience of the use of these in the COPD PREM-9 will give important information not only to the patient but also the healthcare professional.

The COPD PREM-9 has the potential to be used in a number of clinical settings (discussed in Chapter Eight), but in summary, every patient completing the COPD PREM-9 will score each item and each section individually. After completing the questionnaire a total score out of 45 is indicated. In essence the higher the total score the worse the COPD experience.

It was evident that the COPD PREM-9 has good relationships to the concepts of the Department of Health (2011) NHS patient experience framework. This Framework was designed to ensure that the eight concepts of patient-centred care are fundamental to that of patient experience. The framework was not used in any part of the decision making process in the development of the questionnaire. The Framework has however, formulated a strong association across the eight concepts supporting the underlying principles of the experience captured using the COPD PREM-9. The instrument has demonstrated that experiences of COPD can be both positive and negative (good and bad) as set out in the underlying construct of the PREM regardless of severity of COPD. And it could be a useful tool in routine clinical practice.

7.3.4. Correlations with PROMs

As this was the first ever patient experience measure designed specifically for patients with COPD, it is difficult to make correlations through validity with other measures, unlike PROMs where there are a number of different measurements such as the St George's Respiratory Questionnaire or COPD Assessment Test. Currently the measurement of patient experience in COPD is yet unknown. It was evident in the measurement in healthcare that PROMs are used to help explore either an intervention or the management of symptoms and looks at health related quality of life or mood. The COPD-PREM 9 was used within the validation process. Therefore, it was assessed against other commonly used tools within COPD care, and although the results suggest that there is an association between the CAT and the PREM it is quite weak, with only 16% shared variance. This shows that the PREM is measuring something different from impaired health status and mood as measured by the HAD, which showed similar results – which is good evidence for divergent validity. Disler et al., (2014) concluded from their review that any further research should focus on the interventions that address patients' ongoing needs, of which the generation of the COPD PREM-9 is an example, where the instrument can measure a number of points, therefore continuing to assess and re-assess the experience of patients living with COPD.

7.4. Use with PREMs, PROMs and EDQ5 – A recipe for Quality

A key finding of the literature regarding 'experience' is that the collection of patient experience cannot happen in isolation and that to make any difference in the quality of care we provide or commission for patients then patient experience has to be a component of this, alongside other measurements in health such as patient

reported outcomes or other measurements of health status. Reflecting on the work by Robert & Cornwell, (2013, p.20) regarding what is important to patients, it is possible to see that they identified that any future development or implications for the recording of PREMs in the NHS should be covered by the following five fundamental principles:

1. Simultaneously seek to improve accountability, transparency and quality;
2. Align with clinical outcomes (e.g. Patient Reported Outcome Measures);
3. Be evidence-based;
4. Be simple;
5. Be embedded in quality standards (e.g. the ongoing work of the National Institute for Clinical Excellence);

It can be evidenced that the development of the COPD PREM-9 also correlates with these 5 fundamental principles. The tool could be used with other healthcare measures to reflect on the three main areas of quality, these being previously identified by the 2012 NHS Framework that quality is built on accountability, transparency and patient experience.

7.5. Length of Questionnaire

The length of the new COPD PREM-9 was an important aspect to the design of the questionnaire. Even though there were 38 items generated in the preliminary COPD PREM the process of reducing the burden of completing a lengthy questionnaire was evident in the recruitment phase, as potential participants were 'put off' by the initial length of the instrument. This, I suspect, is due to the nature of the disease as breathlessness and high anxiety are part of the symptoms experienced by many with COPD (NICE 2010). To produce an instrument which

had the least number of items but ensures the appropriate level of measurement was an important factor in development, along with the questionnaire appearance and wording (Mccoll et al., 2001). This is supported by Prieto et al., (2003, p.27) who argue that the accessibility of shorter instruments would provide advantages in different settings both in research and clinical practice. They also report that efforts to develop shorter questionnaires or instruments have been generated from using existing questionnaires and reducing items. This supports the notion that the generation of a new, short instrument will add value to the quality of instruments currently used within the COPD population.

7.6. Chapter summary

This chapter presents a discussion of the results and underlying literature, including the Department of Health NHS theoretical framework that supports the evidence of patient experience identified within the rigorous literature review. All nine items developed used the descriptors of patient experience and that specific to COPD. The new instrument has good reliability and validity properties, resulting in a concise and scientifically robust PREM COPD-9, which can be used within everyday clinical practice. This chapter concludes the discussion of the development of a validated and reliable PREM instrument.

CHAPTER EIGHT

CHAPTER EIGHT

8. Conclusions

8.1. Introduction

This final chapter provides a summary of the findings described in the thesis. Suggestions for future work in the field of experience, clinical and research applications of the COPD PREM-9 are presented.

8.2. Summary of Work

This thesis has covered a wide range of topics relating to COPD and the patient experience, and had set the context for the development of a new nine-itemed patient reported experience measure, the generation of a new instrument and understanding the complex language used within patient outcome reporting's. The development of a disease specific PREM hopes to add a new dimension into improving quality of care provided to patients. Providing a patient-centred view of healthcare and of living with the disease is fundamental to the Department of Health patient experience framework. The instrument also has the potential to add a richer dialogue to improve communication, adding value and time to the healthcare professionals consultation with patients, reviewing and reflecting on the answers given.

The conceptual framework guiding this work was based upon a framework developed and agreed by NHS England Quality Board. The concept that experience is multidimensional requiring a number of different aspects but a disease specific instrument needing to reflect the language used by patients to

describe it (Janelle Yorke et al., 2014). This thesis has presented the development and validity testing of a new questionnaire, the COPD PREM-9, which reflects this experience framework as demonstrated in the discussion. This is a unique instrument, since it quantifies experience using the descriptions (words) and items generated by patients for patients. The final three key themes as identified in the COPD PREM development were supported by the relevant qualitative literature in the experience of living with the disease and the interaction with healthcare. Understanding the different aspects of a patients journey from diagnosis to end of life care. The subsequent development of the instrument reduced the themes to three after the diagnosis items were deleted. But it must be acknowledged that, although these items were deleted, subsequent discussion on diagnosis will formulate part of other items on the PREM. The literature also informs us that currently there is no published instrument in COPD of this kind. The COPD PREM-9 is applicable to all severities of COPD patients, regardless of age. Though a larger validation study with a wider population is needed prior to using the instrument further into clinical practice, I am confident that the nine items are relevant, appropriate and capture a wide range of areas relevant to patient-centred care and not the clinician.

It is perceived that the development of instruments are increasingly being created, adapted or translated with little scrutiny regarding their psychometric qualities, their structure, reliability and validity, and therefore, substantial doubts and concerns should emerge regarding their findings. This study has used a robust and commonly reported methodology, using the Rasch model to ensure that items included in the PREM COPD-9 were appropriately scrutinised ensuring appropriate reliability and validity of the instrument. For example, a positive return

rate of 50% of Pack B ensured the stability of the COPD PREM instrument and ensured consistency and appropriate reporting with a higher than expected return rate. The process of item reduction outlined also ensured that items put forward to Rasch were free from bias strengthening the argument that the development of the COPD PREM-9 has good psychometric qualities, structure and reliability and validity.

The aim and objectives (p.103) of the thesis were achieved through the appropriate stages undertaken and set out within the chapters of the thesis. Resulting in a validated patient-centred COPD PREM-9 questionnaire.

8.3. Clinical Implications and Applications

The clinical implications for this COPD PREM-9 are varied and wide. Certainly there is a need to continue to validate its use within clinical practice. The COPD PREM-9 has been shown to a number of patients who participated in the study and completed the initial PREM-38. They were surprised about how concise and easy to understand it was. It was identified that the questions were helpful to express how they felt in a number of different subject areas. There are a number of implications for clinical practice, firstly for the first time we have a questionnaire that is centred around the patient living with COPD and exploring the patient's own experience of living with the disease which is not focussed on the symptoms that are associated to it. There will be associations made about symptoms and the limitations this causes.

The most critical implication for clinical use is the focus on an improvement in communication between patient and healthcare professional by measuring patients experience in a systematic way, the results of the questionnaire will give

the clinician an indication of a total score of experience. But this can then lead to discussion points of areas in which a high score has been given or potential further discussion on where a low score has been given. This improved dialogue between clinician and patient enables a more focussed patient centred approach to COPD care focussing on experience and what matters to patients debate. Improving focussed areas has the potential to increase quality of care delivered to patients living with COPD. This could be done through an audit process using the tool to benchmark practice of experience with appropriate action and subsequent follow-up.

The COPD PREM-9 has the potential to provide a valuable measurement for clinicians to use alongside current PROMs for example the CAT and HAD questionnaires. This PREM has the potential to become the leading measurement of experience in COPD and enable healthcare professionals across the world to improve the experience of patients living with the disease, by understanding the impact experience has in three key aspects of COPD care. There is increasing demand, as the literature and introduction to this thesis suggests that to improve service delivery. The quality and effectiveness of these services needs addressing. This instrument has the potential also to be the first disease-specific instrument to support quality improvement by benchmarking experience scores within improvement programmes to compare scores to facilitate and present findings.

The COPD PREM-9 has already received international coverage at the European Respiratory Society Annual conference (Appendix Ten) and interest in its development and translation and inclusion in research studies and clinical use is growing. The COPD PREM-9 has also been included in the Royal College

of Physicians 5-year National COPD Audit programme, subject to final agreement. This highlights the need for such an experience instrument and helps support the robust methodological and scrutiny this study has undertaken.

8.4. Limitations of the study

There are a number of limitations of this study which will be reported however, limitations become opportunities for future development or review.

A limitation to the study was that a background study identified no measure of COPD experience. There had, however, already been two comprehensive systematic reviews on the experience of people living with COPD up to a certain point; the undertaking of a full systematic review for this thesis was therefore not undertaken. However, a rigorous review of the literature, giving indications of quality review and an update of the literature exposed a number of current papers that helped to generate a greater understanding and influenced this previous understanding of the experience of people living with COPD. And, therefore, as there was no published data on an instrument to measure the experience of people living with COPD, the results from Study One (COPD PREM development) were derived from this learning and cross matched against studies which have explored the severe to very severe groups, giving insight into the older person and the younger person living with COPD.

A key limitation of the study was that the COPD PREM-9 was only developed and currently tested for reliability and validity in England and was only available in certain areas, which is not dissimilar to other instrument development (Trendall & Esmond, 2007). Although there were a number of participants, English was not always their first language. However, this was not recorded so there are no

conclusions or analysis which can be made on this. The validation of any new instrument remains in constant development and further steps are needed in international studies of the PREM COPD-9 to test further its psychometric properties. Use of these standardised techniques will ensure linguistic and cultural validity in a variety of languages (Jones et al., 2009).

Due to the frailty of some of the potential participants and those that agreed to take part in the study, it was identified that some participants were not able to or declined to undertake spirometry at the time of recruitment. This was for many reasons such as a recent exacerbation of COPD, or they had it recently for an annual review. Instead spirometry results were sought from their local general practitioner or hospital. However, this was not always possible for a number of reasons, such as no response from request or spirometry not undertaken recently (within the last year), this left a 16% of spirometry results not collected in the population. Though a broad range of severity was captured in the study.

The rich discussion that was also undertaken in the Breathe Easy and pulmonary rehabilitations groups, as mentioned within the discussion, also helped support many of the items that were deleted. This discussion, however, was not recorded which is a limitation of the study as therefore no thematic analysis of these recordings can be made. However, to understand the lived experience and to understand the discussion that was provoked from all items gave an insight into how the COPD PREM-9 could be used in clinical practice. The 'conversation' that followed after patients answered a question also gave justification for their answer of a good or bad experience, sometimes reflecting on an event or an example of how the item made them feel was useful method of 'validating' the questionnaire through a face-to-face conversation giving effective discussion for future usage.

A further potential limitation relates to the collection of 'rich data'. In the instrument itself there are no free text boxes to collect any qualitative comments from participants. But the concept of the questionnaire was to generate an overall experience score and then use the instrument as a discussion tool with patients to examine where the score is high (worse experience) and use as a prompt to support particular aspects of care.

A key finding from the literature, though not reported is the specific role that carers and families have in the care of loved ones with COPD. The relationships that carers and family also is an accepted and acknowledged aspect of patients care. The literature review touched on this but it is acknowledged that there is a far greater pool of evidence supporting this aspect. The COPD PREM-9 does highlight one item on whether family and friends are involved in care. The concept is highlighted in the NHS patient experience framework and focus on the friends and family test, but further work on measuring the relationship between patients with COPD and families or carers needs, addressing alongside the qualitative work previously undertaken.

A final limitation of the study and its use within clinical practice is the focus on the conflict of terminology and understanding of the words PREMs, PROMs and that of satisfaction by clinicians may hinder the appropriate use and reporting of new tools in the area of patient experience. Unless clinicians themselves are prepared to develop and advocate the traditional thoughts of PREMs and that of the health service. The appreciation that to provide quality care is a continuum of patient experience alongside safety and effectiveness to ensure patient centred care is delivered. A shift of understanding in whether a service was 'good' or 'bad' is a

very different concept to understanding the experience of living with a disease. This has to be the focus of experience moving forward in the NHS.

As previously discussed there are a vast number of PROMs and national patient surveys being used daily to capture organisation change, but how is this person-centred? In COPD, this life-limiting condition, understanding the experience of living with the disease and the potential modifications that can be undertaken in partnership with health related quality of life measurements can for clinicians support and measure intervention, thus giving the clinicians evidence to support clinical expertise focussing on the patient rather than the focus on the money, length of stay or number of acute admissions avoided. The misunderstanding of terminology is not just isolated to junior nurses and staff many senior clinicians have to have a greater understanding of the use of PREMs in clinical practice. It is hoped that this thesis will help inform this direction.

8.5. Future Direction for Research

The underlying aim of the study was to generate an instrument that was developed for COPD patients by COPD patients ensuring that the language used in the final COPD PREM-9 was able to be understood by the COPD population and that patients were able to relate to the underlying construct of the experience of patients living with COPD. The first direction of the COPD PREM-9 is to undertake a reliability and validity study of the final 9 items, although the items were examined for reliability and validity and identified as having a unidimensional fit to the Rasch. An exploratory study of the 9 items in a different cohort of COPD patients recruited through the same means including a test-re-test design method

would support the validity of the final instrument. This would allow the COPD PREM-9 to be used and generate further interest and testing its use more widely.

Further work needs to be completed in the instructions and recommendations to compliment the use of the COPD PREM-9. These include making a series of levels according to a score range, and narrative with a list of recommendations and advice if a patient scores a high score indicating a bad experience and strategies and advice on how potentially this could be lowered increasing the patients experience. Future work with patients and healthcare professionals in a series of workshops is planned.

The majority of participants in the testing and validation of the PREM COPD-9 were white British with English as their first language. Validation of the PREM COPD-9 in other languages and cultures would entail translation of the instrument. However, as the COPD PREM-9 was developed in the UK for European or international use would need a review of the items within this as for some EU countries the term General Practitioner is not known, and other meanings such a 'family doctor or physician' are more common terms. The view of future testing and translation of the new instrument into other languages and its validity testing is needed and I suspect welcomed.

This instrument is on a journey and although the journey end point for its initial development has been completed, the roll out and embedding the instrument into practice has just begun. The next stage in the instrument's longevity is to undertake a further reliability study which includes testing the COPD PREM-9 in a different cohort of people living with COPD. These would be recruited with participants who did not participate in Studies A and B. This would be undertaken

as a research study using a similarly sized recruitment pool, further assessing construct validity and reliability with participants. However, there are issues around the time and recruitment of these participants. Further concern with the roll out would also include 'control' over the possible number of ongoing studies which would have also been suggested in larger, discrete COPD populations using different severities of COPD, and translation and diffusion in different languages. However, these developments would be completed within a controlled way ensuring appropriateness which includes ensuring intellectual property and copyright remain within the PREM expert group and working in partnership to develop these potential studies further. But the instrument would not be made 'public' until appropriate publication of the development of items and subsequent development and testing were published and referenced. The vision is for the instrument to be free to access and it is hoped a website would be created for healthcare professionals to utilise and download it, thereby sharing information and further research on the COPD PREM-9 as its vision develops.

Further work is also needed with COPD patients and respiratory experts to review the advice and criteria on the total scoring of the instrument along with further research in testing the instrument in the advice areas to gain a greater understanding of whether the instrument is sensitive enough to detect change and/or be a useful benchmark or quality indicator in COPD. An example of this would be to undertake a study using the instrument as an outcome measure pre- and post- pulmonary rehabilitation, of which a number of quality of life and outcome measures are already used. But a short experience measure has not been undertaken and has the potential to add individual dialogue with the clinician and patient on areas that potentially the patient scores highly (bad experience).

Responsiveness of COPD PREM-9 was assessed in the validation of the instrument using a patient's self-report of change in their general health. Responsiveness of a questionnaire to change is an important psychometric property for assessing benefit to 'intervention' for a change in experience. The COPD PREM-9 must go through further rigorous testing to explore its sensitivity to change and responsiveness to intervention before being accepted as a tool used as an outcome measure used in routine care. However, after further testing it should be appropriate for use in studies of a wide range of treatment areas including nurse-led intervention in education and self management techniques, along with pulmonary rehabilitation and possibly drug trials. Further research is also needed in using the PREM COPD-9 alongside other widely used outcome measures in these areas too. Suggested complimentary instruments could include the CAT, St Georges Respiratory Questionnaire and the COPD questionnaire.

The COPD PREM-9 also needs to be explored further larger populations in specific younger population even though the study had a variety of age groups the mean was 71 years and further exploration of the working COPD population is needed.

8.6. Reflection on the Thesis process

The Nursing and Midwifery Council (NMC) encourages nurses to reflect on individual areas in order to ensure that there are examples of evidence which are evaluated and concise, enabling nurses to maintain high quality patient-centred care (RCN, 2011). The NMC code of professional conduct highlights two key points (NMC., 2008, p,6):

You must keep your knowledge and skills up to date throughout your working life

You must take part in appropriate learning and practice activities that maintain and develop your competence and performance

These two statements from the code underpin the acts upon how nurses learn and how experience underpins their own learning from this to undertake critical performance and demonstrate competency. Nurses practising in today's rapidly changing National Health Service are increasingly responding to the need to evaluate and review services as well as considering the political, social and organisational issues affecting evidence (Dhabi, 2003), even more evident in the background context discussed in Chapter One. As change happens daily, it is important for nurses to be able to analyse and respond to new challenges proactively. Having critical thinking and reflective skills has assisted me to challenge traditions and boundaries in the development of this instrument, to develop a tool that could support other nurses to deliver effective and cost-efficient evidence-based patient care, exploring the key concepts in COPD care. Currently we are working in rapid change, and to understand fully the context of reflection and how the concept of my experience can be fully understood in its relationship to reflective practice is maintained within practice. The learning theory that underpins nursing practice is the backdrop of my everyday practice which has helped expand my critical thinking to develop a direction of work from what I have understood through my own experience of this thesis' journey. Chinn & Kramer, (2007, p.182) suggest that a theory is

a creative and rigorous structuring of ideas that projects a tentative, purposeful and systematic view of phenomena

This suggests that ideas and learning are generated through the notion of experience and observation and are open to new evidence as insights emerge. As a critical reflective practitioner the process of reflection on my work is fundamental and therefore can be embedded into my learning process (Chinn & Kramer, 2008). The development of this thesis has enabled me to reflect upon how the experience in learning new skills such as the Rasch Model and the combination of statistics and words can work together to ensure that the value of experience can be approached or seen in many different ways, illustrating that nurses can use different models of developing and generating new ideas through the support of learning through reflection and action setting the scene for new concepts, models and behaviours. These can be related to how patients also can use experience in their interactions with healthcare staff and the impact of disease on quality of life.

8.7. Concluding Remarks

The work described in this thesis conveys the development and first validation of a new nine itemed experience instrument. In doing so, it has examined the research aim and objectives that underpinned this thesis, that qualitative descriptors can be used to develop an experience questionnaire in COPD. The COPD PREM-9 outlines that the recording of experience descriptors of living with COPD can be documented in a concise instrument that differs to commonly used outcome measures with COPD in clinical practice.

The COPD PREM-9 was shown to have reliable and valid measurement properties in the measurement of experience in patients with COPD. It potentially has wide application in studies designed to assess experience in a range of

clinical settings such as pulmonary rehabilitation, and the potential to be used alongside other outcome measures in therapeutic studies, along with the potential to become a quality improvement tool. However, further work is needed to assess the application of the COPD PREM-9 in different clinical settings. This includes a further validation study of the final 9-item questionnaire with a different cohort of COPD patients across a broad spectrum of severities and demographics. Additional work is also needed to support clinicians in the practicalities and guidance of the everyday application of the questionnaire. This will be done with clinical and patient engagement in a provision of suggested resources and instructions of 'areas' to improve experience dependent on a total experience score. Further work and research is needed to examine and understand the individual patient clinical benefit that the COPD PREM-9 will have as an experience outcome to improve patient care, for example in areas such as pulmonary rehabilitation and COPD nurse-led case management, both of which provide COPD specific intervention aimed at improving the knowledge and confidence of COPD. Further 'control' of the instrument is also needed to work alongside potential researchers who may wish to use the instrument in 'research' and 'clinical practice' and work in partnership to collect questionnaire results to be used potentially in audit as a marker of quality or service development.

Likewise, the impact of experience on different parts of a patient's journey, and how this varies between different severities and age groups, is warranted.

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APPENDICES

Appendices

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APPENDIX ONE

NECLES HIEC

**Developing a Patient Reported Experience Measure
for Chronic Obstructive Pulmonary Disease
(PREM-COPD)**

Final Report

22 February 2012



**Royal College
of Physicians**



**CITY UNIVERSITY
LONDON**

picker
Institute Europe



British Lung Foundation



**British
Thoracic
Society**

NECLES HEIC

Developing a Patient Reported experience Measure (PREM) in COPD

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EXECUTIVE SUMMARY

The NECLES HIEC in collaboration with The Royal College of Physicians, British Thoracic Society, British Lung Foundation, Picker Institute, City University and Anglia Ruskin University collaborated in the development of a Patient Reported Experience Measure (PREM) for use in all Chronic Obstructive Pulmonary Disease patients (COPD).¹ The PREM-COPD is a move away from traditional medical model questionnaires, to look at the patient journey with COPD and identify the principle moments of quality care and affective experiences which will then make it possible to benchmark future service provision.

Our aim is to create a valid and reliable Patient Reported Experience Measure for patients with COPD and in doing so, provide a response to the Government's White Paper "Equity and Excellence, Liberating the NHS"² which puts the patient experience and patient outcomes as the metrics for quality improvements in healthcare.

The experiences of a 64 patients with COPD across the community of North East London, North Central London and Essex (NECLES) region, with a range of severity and presentation and 19 patients with recent hospitalisation due to COPD related conditions were captured. The experiences for both groups were grouped and coded separately leading to the development of items pertaining to both patient groups.

Twenty Affective (emotive or felt) responses were identified from patient responses. Negative Affective responses described by both the community and hospital patient groups included: scared; anxiety; worry; fear / frightened; frustration; annoyance / anger; confusion; embarrassment; surprise / shock. The negative Affective response "feeling depressed", was only identified in the community group responses and guilt was only in the hospital group.

Positive Affective responses identified for both groups were: gratitude; reassured and happy / enjoyment. Altruism, hope and acceptance were also mentioned in the community group.

Self-motivation, control and respect were either Negative or Positive Affective responses according to their context with the first two only identified in the community group.

The community patient group experience centred around 5 categories:

- **“Journey to diagnosis”**
 - This journey left patients frightened, frustrated, surprised and shocked
- **“Smoking”**
 - Self-motivation and being scared by their diagnosis or the symptoms associated with COPD led some patients to give up smoking
- **“Usual care (communication, staff and managing routine care)”**
 - Lack of, or poor communication, or the manner of communication with health professionals, left patients feeling frustrated, annoyed, confused and angry
- **“Exacerbation”**
 - This can frighten, scare, confuse, frustrate and depress patients
- **“My everyday life”**
 - The limitations of living with COPD are described as frustrating, annoying, worrying, depressing and embarrassing

The **“Hospital”** patient experience pivoted around 5 categories:

- Going to hospital
- On arrival to hospital
- On the ward
- Discharge from hospital
- Follow-up care

Preliminary items from the Affective responses for both patient groups have been developed and will undergo pilot testing with the aim of establishing reliability and validity of the PREM-COPD.

Completion of this testing will result in a sensitive and reliable PREM that can be used to measure self- defined important experiences of patients when using healthcare services.

Roberts, M., Andrew, S., Walker, S., Hodson, M., & Hudson, R. (2012). Developing a patient reported experience measure for COPD. European Respiratory Journal, 40(56), P1464.

Presented at ERS Conference Vienna 2012

Abstract

Introduction The patient experience and patient outcomes are metrics for quality improvements in healthcare. There is no currently available patient reported experience measure (PREM) for COPD.

Study Aim The aim of the study is to create a valid and reliable PREM for patients with COPD.

Methods Sixty four people with COPD across the community of North East London, North Central London and Essex and 19 with recent hospital experience were interviewed to capture their patient journey with COPD. Analysis of the interview data was by a two layer approach: *content* and then by *affective* (emotive or felt) responses.

Results Eighteen different *affective* responses were described by patients and were grouped as positive, negative or ambivalent. Positive responses included: hope, gratitude, comfort/ reassured, acceptance, optimism, altruism, happy and respect. Negative responses included scared, anxiety, fear, frustration, worry, feeling depressed, denial and embarrassment. 'Self-motivation' and control were contextual and could be either positive or negative.

The community patient groups' experience centred around five categories identified in the content analysis: 'Journey to Diagnosis'; 'Smoking'; 'Usual Care'; 'Exacerbation ('flare-up)' and 'My Everyday Life'. The hospital patient experience was categorised as: 'Going to Hospital'; 'On Arrival to Hospital'; 'On the Ward'; 'Discharge from hospital' and 'Follow-up care'. Items based on patients 'affective responses were generated from the categories to develop a PREM-COPD scale.

Conclusion Completion of the testing of the PREM-COPD will result in a valid and reliable instrument to be used to measure self-defined important patient experiences when using healthcare services.

APPENDIX TWO

NHS Patient Experience Framework

In October 2011 the NHS National Quality Board (NQB) agreed on a working definition of patient experience to guide the measurement of patient experience across the NHS. This framework outlines those elements which are critical to the patients' experience of NHS Services.

- **Respect for patient-centred values, preferences, and expressed needs**, including: cultural issues; the dignity, privacy and independence of patients and service users; an awareness of quality-of-life issues; and shared decision making;
- **Coordination and integration of care** across the health and social care system;
- **Information, communication, and education** on clinical status, progress, prognosis, and processes of care in order to facilitate autonomy, self-care and health promotion;
- **Physical comfort** including pain management, help with activities of daily living, and clean and comfortable surroundings;
- **Emotional support** and alleviation of fear and anxiety about such issues as clinical status, prognosis, and the impact of illness on patients, their families and their finances;
- **Welcoming the involvement of family and friends**, on whom patients and service users rely, in decision-making and demonstrating awareness and accommodation of their needs as care-givers;
- **Transition and continuity** as regards information that will help patients care for themselves away from a clinical setting, and coordination, planning, and support to ease transitions;
- **Access to care** with attention for example, to time spent waiting for admission or time between admission and placement in a room in an in-patient setting, and waiting time for an appointment or visit in the out-patient, primary care or social care setting.

This framework is based on a modified version of the Picker Institute Principles of Patient-Centred Care, an evidence based definition of a good patient experience. When using this framework the NHS is required under the Equality Act 2010 to take account of its Public Sector Equality Duty including eliminating discrimination, harassment and victimisation, promoting equality and fostering good relations between people.



APPENDIX THREE

Development of a COPD Patient Reported Experience Measure (PREM) Stage 2



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- Professor M Roberts
- Professor S Andrews
- Professor P Jones
- British Lung Foundation Representation
- COPD National Audit Programme Manager

Breathe Easy Group Patient Representation

Overview

PREM Stage 1

PREM Stage 2 – Part A

- recruitment process & ethical clearance
- baseline demographics
- hierarchical methods of item reduction
- understanding of the Rasch Model
- item removal in Rasch
- summary of fit and decisions on items
 - conclusion and final items

Introduction – Stage 1

- Development of PREM Concept
- 83 Interview patients across the NECLES region on experience of living with COPD
- Thematic analysis and themes identified
 - 20 Affective (emotive or felt) responses were identified
 - 5 themes identified (journey to diagnosis, smoking, usual care, everyday life, exacerbation, information provision)

Stage 2: COPD-PREM – initial item list

Part A PREM – Everyday life with COPD

- 40 Items into the 5 themes
- 38 Items into the Draft PREM COPD (2 removed)

Part B PREM – Hospital related care

- 14 Items

Stage 2

Ethical approval by Bloomsbury REC

COPD Patients recruited from (n = 174)

- London (n = 120)
- Portsmouth (n = 19)
- Manchester (n = 15)
- Guernsey (n = 8)
- Essex (n = 5)
- Norwich (n = 7)
- Hospital and Breathe Easy Groups

Part A PREM - Demographics

Demographics:

- 174 participants
- 83 male and 91 female
- Age (mean: 71years; SD: 9.1; range: 42 – 91)
- FEV₁% (mean: 59%; SD: 21.9; range: 11% - 92%)
- FVC/FEV Ratio: (mean: 50%; SD: 20.4; range: 23-75%)
- CAT Score (mean: 20; SD: 8.5; range: 2 – 40)
- MRC: 1 = 4; 2 = 32; 3 = 53; 4 = 42; 5 = 31

PREM A – Item Reduction Protocol

Hierarchical methods of item reduction:

- missing data at > 15%
- floor affect > 40%
- ceiling affect > 40%
- gender bias* – Mann Whitney-U Test
- age correlation* – Spearman's Correlation
- Item-item correlation - r value > 0.80

*p = < 0.01

Items flagged for removal					
Question No	Question (Low Score Answer)	Missing >15%	Floor > 40%	Age Correlation	R Value
1	I am not shocked by my COPD diagnosis				
2	I have come to terms with my diagnosis of COPD				
3	I have given up smoking and I am confident that I will not start	x			
4	I want to stop smoking and I believe I can	x			
5	It was a relief to have a diagnosis for my symptoms	x			
6	I understand my diagnosis		x		
7	I am confident that my GP will listen to my point of view		x		Q13
8	I am very pleased with health care workers		x		Q13
9	I am happy with the length of time to see GP				Q11
10	I really enjoyed pulmonary rehabilitation	x	x		Q11
11	I found pulmonary rehabilitation useful	x	x		Q11
12	I understand my condition and this helps me to manage my fear		x	x	Q8
13	The information I have been given is consistent		x		
14	I have enough information about my condition		x		
15	I understand about my COPD tablets	x			
16	I am confused about how to use my COPD inhalers				
17	I understand how my COPD treatments work		x		
18	I don't find going to a hospital outpatient clinic frustrating		x		
19	I know how to use my inhaler properly		x		
20	I have accepted the limitations to my lifestyle caused by COPD				
21	I feel that I have good support from others				
22	Overall I am satisfied with my life				
23	I am not depressed		x		
24	Overall I am satisfied with the care given to me		x		
25	I am not embarrassed to tell others about my condition		x		
26	I feel that I am in control of my condition		x		
27	I am motivated to keep going and to not give up		x		
28	I am happy to talk about the future		x		
29	I am not concerned about the future			x	
30	I am not worried about the season			x	
31	I keep going and try to enjoy my life		x	x	
32	I am confident in a 'flare up' I have quick access to treatment			x	
33	I do not feel anxious about my current health				
34	I am not worried about the care I will get with 'flare-up'			x	
35	I am not scared of getting a cold or an infection				
36	I am not frightened of being breathless when I have a 'flare-up'			x	
37	I am not frightened to go to sleep 'flare-up'			x	
38	I try not to panic when I have a 'flare up'				

p = < 0.01

Item Removed			
Question No.	Question (Low Score Answer)	Yes	No
1	I am not shocked by my COPD diagnosis		x
2	I have come to terms with my diagnosis of COPD		x
3	I have given up smoking and I am confident that I will not start	x	
4	I want to stop smoking and I believe I can	x	
5	It was a relief to have a diagnosis for my symptoms	x	
6	I understand my diagnosis	x	
7	I am confident that my GP will listen to my point of view		x
8	I am very pleased with health care workers	x	
9	I am happy with the length of time to see GP		x
10	I really enjoyed pulmonary rehabilitation	x	
11	I found pulmonary rehabilitation useful	x	
12	I understand my condition and this helps me to manage my fear	x	
13	The information I have been given is consistent	x	
14	I have enough information about my condition		x
15	I understand about my COPD tablets	x	
16	I am confused about how to use my COPD inhalers		x
17	I understand how my COPD treatments work		x
18	I don't find going to a hospital outpatient clinic frustrating	x	
19	I know how to use my inhaler properly	x	
20	I have accepted the limitations to my lifestyle caused by COPD		x
21	I feel that I have good support from others		x
22	Overall I am satisfied with my life		x
23	I am not depressed	x	
24	Overall I am satisfied with the care given to me	x	
25	I am not embarrassed to tell others about my condition	x	
26	I feel that I am in control of my condition		x
27	I am motivated to keep going and to not give up	x	
28	I am happy to talk about the future		x
29	I am not concerned about the future	x	
30	I am not worried about the season	x	
31	I keep going and try to enjoy my life	x	
32	I am confident in a 'flare up' I have quick access to treatment		x
33	I do not feel anxious about my current health	x	
34	I am not worried about the care I will get with 'flare-up'		x
35	I am not scared of getting a cold or an infection	x	
36	I am not frightened of being breathless when I have a 'flare-up'	x	
37	I am not frightened to go to sleep 'flare-up'		x
38	I try not to panic when I have a 'flare up'		x

Professional Review (see no. 0)

Additional 3 items removed:

- 1 - not shocked by diagnosis
- 37 – not frightened to go to sleep during a flare-up
- 38 – try not to panic with a flare-up

Reasons:

- Not general items of healthcare experience
- Poor spread across severity of COPD
- Patient feedback - confusing item (Q1)

Items* entered into Rasch (see no. 1)

Question No	Question (Low Score Answer)
2	I have come to terms with my diagnosis of COPD
7	I am confident that my GP will listen to my point of view
9	I am happy with the length of time to see GP
14	I have enough information about my condition
16	I am confused about how to use my COPD inhalers
17	I understand how my COPD treatments work
20	I have accepted the limitations to my lifestyle caused by COPD
21	I feel that I have good support from others
22	Overall I am satisfied with my life
26	I feel that I am in control of my condition
28	I am happy to talk about the future
32	I am confident in a 'flare up' I have quick access to treatment
34	I am not worried about the care I will get with 'flare-up'

*n= 13

Initial Summary of Statistics*

	Item Location		Person Location		Item fit Residual		Person Fit Residual		Chi Square Interactions			PSI
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Value	df	p	
Initial: Run	0	0.29	-0.76	1.13	0.24	2.37	-0.25	1.50	87.81	26	0.000	0.80

*n= 13

3 Items deleted due to mis-fit:
 2 – 'have come to terms with COPD'
 9 – 'happy with time taken to see GP'
 16 – 'confused about how to use inhalers'

Summary of Statistics – Rasch Fit

	Analysis	Item Location		Person Location		Item fit Residual		Person Fit Residual		Chi Square Interactions			PSI
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Value	df	p	
Deleted Q16	DL16	0	0.20	-0.87	1.20	0.29	1.69	-0.28	1.60	56.9	24	0.000168	0.80
Deleted Q9	DL9	0	0.15	-0.94	1.30	0.30	1.22	-0.31	1.56	36	22	0.03	0.80
Deleted Q1	DL2*	0	0.15	-0.99	1.40	0.20	0.87	-0.52	2.38	22.2	20	0.328	0.77
Deleted Q22	DL22**	0	0.12	-1.01	1.49	0.36	0.95	-0.47	2.10	14.2	18	0.71	0.75
Deleted Q21	DL21***	0	0.11	-0.99	1.50	0.43	1.10	-0.51	2.38	17.3	16	0.363	0.73

10 item solution*
 9 item solution**
 8 item solution***

Individual Item Fit – 10 item solution

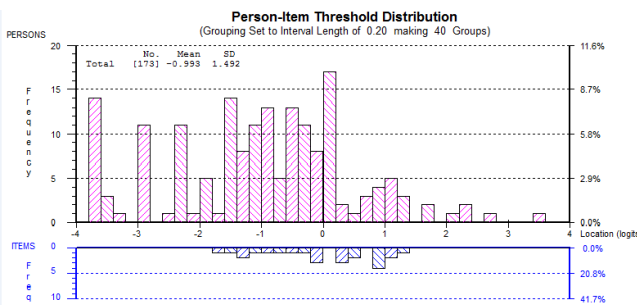
INDIVIDUAL ITEM-FIT for Analysis Name DL2 - Location Order

Seq	Item	Type	Location	SE	FitResid	DF	ChiSq	DF	Prob	F-stat	DF-1	DF-2	Prob
6	9	22	Poly	-0.320	0.115	0.920	123.78	0.241	2	0.996296
3	6	17	Poly	-0.090	0.149	-0.455	119.39	2.071	2	0.354992
2	4	14	Poly	-0.081	0.108	-0.978	122.02	1.860	2	0.394484
10	13	34	Poly	-0.080	0.154	0.246	120.26	0.422	2	0.809628
8	11	28	Poly	-0.021	0.144	-1.105	124.65	3.243	2	0.197841
9	12	32	Poly	-0.011	0.110	1.229	122.90	5.292	2	0.070926
7	10	26	Poly	0.055	0.116	-0.388	124.65	4.908	2	0.085930
1	2	7	Poly	0.167	0.135	0.997	125.53	2.955	2	0.228222
4	7	20	Poly	0.190	0.141	1.038	127.29	1.034	2	0.596450
5	8	21	Poly	0.190	0.136	0.547	125.53	0.205	2	0.902355

Mean	Std Dev	Totals	Total Prob
0.000	0.205	22.233	0.328022
0.159	0.876		

Selection: 5 Item Statement: 21
 Sort Items by: Location Order
 File Text Format: Fixed
 Tab Delim: Copy
 Highlight extm FitResid values. Set at: +/- 2.5
 Highlight probabilities below the Bonferroni adjustment

Person-Item Map – 10 item solution



Individual Item Fit – 10 item solution

INDIVIDUAL ITEM-FIT for Analysis Name DL2 - Location Order

Seq	Item	Type	Location	SE	FitResid	DF	ChiSq	DF	Prob	F-stat	DF-1	DF-2	Prob
6	9	22	Poly	-0.320	-0.115	0.620	123.79	0.241	2	0.696296
3	6	17	Poly	-0.090	0.149	-0.455	119.39	2.071	2	0.354992
2	4	14	Poly	-0.081	0.108	-0.978	122.02	1.860	2	0.394484
10	13	34	Poly	-0.080	0.154	0.246	120.26	0.422	2	0.609628
8	11	28	Poly	-0.021	0.144	-1.105	124.65	3.243	2	0.197841
9	12	32	Poly	-0.011	0.110	1.229	122.90	5.292	2	0.070926
7	10	26	Poly	0.055	0.116	-0.388	124.65	4.908	2	0.065930
1	2	7	Poly	0.167	0.135	0.997	125.53	2.955	2	0.228222
4	7	20	Poly	0.190	0.141	1.038	127.29	1.034	2	0.596450
5	8	21	Poly	0.190	0.136	0.547	125.53	0.205	2	0.902355

Deleted item 22

Mean	0.000	0.205	Totals	22.233	20
Std Devn	0.159	0.876	Total Prob	0.328022	

Selection: 5 Item Statement: 21

Sort Items by: Location Order

File Text Format: Fixed Tab Delim

Highlight extm FitResid values. Set at: +/- 2.5

Highlight probabilities below the Bonferroni adjustment

Copy Resp Types Chi Squ

Individual Item Fit – 9 item solution

INDIVIDUAL ITEM-FIT for Analysis Name DL22 - Location Order

Seq	Item	Type	Location	SE	FitResid	DF	ChiSq	DF	Prob	F-stat	DF-1	DF-2	Prob
9	13	34	Poly	-0.134	0.157	0.273	113.40	0.322	2	0.851225
3	6	17	Poly	-0.126	0.152	-0.585	112.53	3.339	2	0.188376
2	4	14	Poly	-0.106	0.109	-1.266	115.13	4.131	2	0.126775
7	11	28	Poly	-0.056	0.145	-0.574	117.72	2.357	2	0.307783
8	12	32	Poly	-0.046	0.111	1.150	115.99	1.281	2	0.526969
6	10	26	Poly	0.006	0.117	1.036	117.72	0.826	2	0.661777
1	2	7	Poly	0.149	0.136	1.263	118.59	1.659	2	0.436242
4	7	20	Poly	0.156	0.142	1.250	120.32	0.112	2	0.945652
5	8	21	Poly	0.160	0.137	0.734	118.59	0.262	2	0.877288

Mean	0.000	0.365	Totals	14.286	18
Std Devn	0.124	0.952	Total Prob	0.710146	

Selection: 9 Item Statement: 34

Sort Items by: Location Order

File Text Format: Fixed Tab Delim

Highlight extm FitResid values. Set at: +/- 2.5

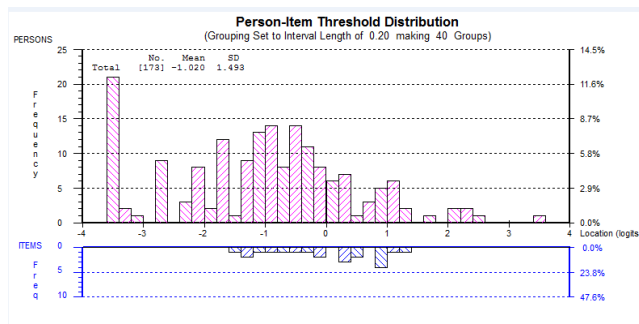
Highlight probabilities below the Bonferroni adjustment

Select Probability Base: 0.01

Adj = 0.001111 for 9 items

Copy Resp Types Chi Squ

Person-Item map – 9 item solution



9 item fit

Individual Item Fit – 9 item solution

INDIVIDUAL ITEM-FIT for Analysis Name DL22 - Location Order

Seq	Item	Type	Location	SE	FitResid	DF	ChiSq	DF	Prob	F-stat	DF-1	DF-2	Prob
9	13	34	Poly	-0.134	0.157	0.273	113.40	0.322	2	0.851225
3	6	17	Poly	-0.126	0.152	-0.585	112.53	3.339	2	0.108376
2	4	14	Poly	-0.100	0.109	-1.286	115.13	4.131	2	0.126775
7	11	28	Poly	-0.058	0.145	-0.574	117.72	2.357	2	0.307783
8	12	32	Poly	-0.048	0.111	1.150	115.99	1.281	2	0.526969
6	10	26	Poly	0.006	0.117	1.036	117.72	0.826	2	0.661777
1	2	7	Poly	0.149	0.136	1.263	118.59	1.659	2	0.436242
4	7	20	Poly	0.150	0.142	1.250	120.32	0.112	2	0.945852
5	6	21	Poly	0.160	0.137	0.734	118.59	0.262	2	0.877288

Deleted item 21

Mean	Std Dev	SE	Totals	Total Prob
0.000	0.124	0.952	14.286	0.710146

Selection: 9 Item Statement: 34

Sort Items by: Location Order

File Test Format: Fixed Tab Delim

Highlight extm FitResid values: Set at: +/- 2.5

Highlight probabilities below the Bonferroni adjustment: Select Probability Base 0.01

Adj = 0.001111 for 9 items

< Display Control Save Copy Resp Types > Chi Sq >

Individual Item Fit – 8 item solution

INDIVIDUAL ITEM-FIT for Analysis Name DL21 - Location Order

Seq	Item	Type	Location	SE	FitResid	DF	ChiSq	DF	Prob	F-stat	DF-1	DF-2	Prob
8	13	34	Poly	-0.124	0.155	0.257	119.52	0.345	2	0.841767	---	---	---
3	6	17	Poly	-0.109	0.153	-0.670	109.67	4.294	2	0.116835	---	---	---
2	4	14	Poly	-0.087	0.110	-1.211	112.22	3.979	2	0.136793	---	---	---
6	11	28	Poly	-0.035	0.145	-0.402	114.78	3.010	2	0.222989	---	---	---
7	12	32	Poly	-0.028	0.111	1.348	113.07	3.745	2	0.153785	---	---	---
5	10	26	Poly	0.033	0.117	0.977	114.78	0.686	2	0.709555	---	---	---
1	2	7	Poly	0.166	0.136	1.791	115.63	1.080	2	0.582661	---	---	---
4	7	20	Poly	0.183	0.142	1.425	117.33	0.203	2	0.903680	---	---	---

Mean	0.000	0.439	Total	17.540	16
Std Dev	0.119	1.109	Total Prob	0.363909	

Selection: 4 Item Statement: 20

Sort Items by: Location Order

File Test Format: Fixed

Tab Delim

Copy

Best Types

Chi Squ

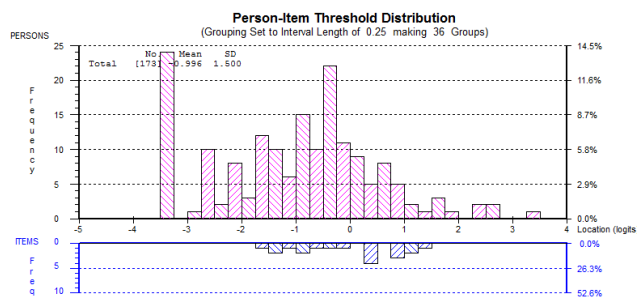
Highlight extra FitResid values. Set at: +/- 2.5

Highlight probabilities below the Bonferroni adjustment

Select Probability Base: 0.01

Adj = 0.001250 for 8 items

Person-Item map – 8 item solution



Final 10, 9 or 8 items (see no. No 4)

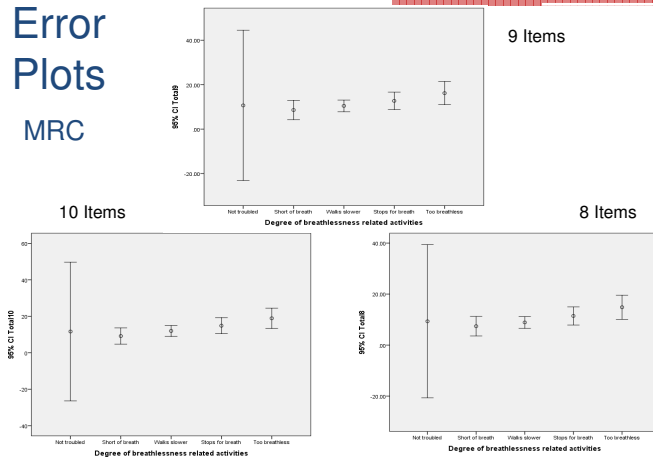
7	I am confident that my GP will listen to my point of view	Usual Care /Primary Care
14	I have enough information about my condition	Usual Care /Information
17	I understand how my COPD treatments work	Usual Care /Treatments
20	I have accepted the limitations to my lifestyle caused by COPD	Everyday Life/ Physiology
21	I feel that I have good support from others	Everyday Life
22	Overall I am satisfied with my life	Everyday Life
26	I feel that I am in control of my condition	Everyday Life/PR
28	I am happy to talk about the future	Everyday Life /Palliative Care
32	I am confident in a 'flare up' I have quick access to treatment	Exacerbation
34	I am not worried about the care I will get with 'flare-up'	Exacerbation

Discussion Points

- Need to decide which solution we use:
 - 10 items ICC 0.78
 - 9 items ICC: 0.78
 - 8 items ICC 0.77
- Discuss process for Part B – Hospitalisation related questions

Error Plots

MRC



Correlations

	CAT Score*	Anxiety*	Depression*
Total 10	.46	.33	.46
Total 9	.42	.30	.41
Total 8	.44	.31	.42

*R value

*Significant less than .001

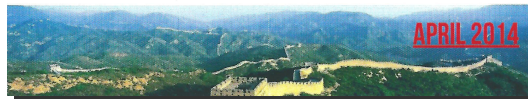
Thank you ...any questions?

matthew hodson

MY GREAT-WALK IN CHINA
TO RAISE MONEY FOR THE BLF

please sponsor me, go to:

virginmoneygiving.com/speak2matt



APPENDIX FOUR



Royal College
of Physicians



University of
Portsmouth

Homerton University Hospital



NHS Foundation Trust

COPD PREM – Data Collection Tool

Study No:

Study Centre	
Researcher Name / Contact	

Patient information Sheet given	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Consent Form Signed	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Participant specific information

Confirmed Diagnosis of COPD	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Has the participant had a flare up in the last 3 months?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Did this require hospital admission?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Spirometry: Date undertaken: _____ (within the last year)

FEV1 % Predicted	%
FVC	L %
FEV/FVC ratio	%
Severity	

Questionnaire Record

Questionnaire	Score
38 PREM-COPD Questionnaire	
CAT Score	
HAD Score	A= D=
MRC Score	

PREM – COPD Questionnaire

38 PREM-COPD Questionnaire – Follow-up	Received:
Global Rate of Change	

Contact details:

APPENDIX FIVE



PATIENT INFORMATION SHEET

The development of a patient reported experience measure in
Chronic Obstructive Pulmonary Disease (COPD)

1 Study Title

The development of a patient reported experience measure in Chronic Obstructive Pulmonary Disease (COPD) – Stage II

2 Invitation paragraph

You are being invited to take part in a research study. This study is part of Matthew Hodson's Professional Doctorate in Nursing. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others such as family, carers or your GP about the study if you wish. Please also ask us if there is anything that you do not understand or you would like more information. Take time to decide whether or not you wish to take part. This study has been approved by North West London - Bloomsbury Research Committee.

3 What is the purpose of the study and why have I been chosen?

The purpose of the research study is to develop a questionnaire. We want to find out about the experience of people who have been diagnosed with the lung condition chronic obstructive pulmonary disease (COPD). We recently interviewed over 80 people who live with COPD to learn about their experiences of interaction with healthcare professionals or services regarding COPD; this may have been a local GP or respiratory nurse (Stage I). The purpose of the interviews are to design a patient reported experience questionnaire that can inform services about how well you feel the services are running and find out what is important to you. A draft questionnaire of 52 items was developed from the interviews. We now wish to reduce and refine this item list to develop the final questionnaire.

You have been chosen because you have a diagnosis of COPD and you have been in recent contact with a healthcare professional or been admitted to hospital because of your COPD.

4 Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

5 What are the alternatives?

If you decide that you do not wish to take part in this study, you are more than welcome keep this information sheet and to contact a member of the research team on 020 8510 5107.

6 What will happen to me if I take part?

You will be asked to sign a consent form stating that you agree to completing the questionnaires either in the clinic with or without the researcher present. Or, you may take this information sheet, consent form and questionnaires home with you to consider participation and complete the contact form (your name and telephone number) so that the researcher (s) may contact you within 24-48 hours later to ascertain your interest in the study.

If you choose this option and decide to take part, the researcher will request that you sign the consent form and return this with the completed questionnaires, using the stamped-addressed envelope provided. The researcher will be available on the telephone to offer assistance in completing the questionnaires.

7 What do I have to do?

We ask all participants to complete and sign a consent form. Demographic data (Spirometry, age, gender, diagnosis, medications, previous hospital admissions, flare-up and smoking history) will be collected by the researcher from your medical notes.

You will be requested to complete 4 questionnaires, including the 52 item list, quality of life questionnaire, and a questionnaire that assesses activity limitation due to breathlessness. Approximately 7 days later, you will be requested to repeat the 52 item list and to answer a single question asking if you think your health has changed since completing the first batch of questionnaires. You will be provided with a stamped-addressed envelope to return the completed questionnaire to the researcher.

8 Will my taking part in this study be kept confidential?

If you take part in the study you will be given a unique study number to ensure that none of your details will be known outside the research team. All information which is collected about you during the course of the research will be kept strictly confidential. If you consent to take part in the research the people conducting the study will abide by the Data Protection Act 1998, and the rights you have under this Act.

You also have the right to check the accuracy of data held about you and correct any errors.

9 Expenses and payments:

Unfortunately there is no reimbursement for taking part in this study.

10 What are the other possible disadvantages and risks of taking part?

We envisage that there are no disadvantages or risks to taking part in this study. But we hope that this study will help us to improve the care that people with COPD receive in the future.

11 What happens if there is a problem?

While answering the questionnaire if there are any particular issues please speak with your respiratory specialist [Insert Name of local collaborator] on [inset telephone no.] or we would advise that you speak directly to your GP.

We would not expect you to suffer any harm or injury because of your participation.. If you are harmed by taking part in this study, there is no special compensation arrangement. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay your legal costs. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please contact Matthew Hodson, NECLES Fellow on 020 8510 5107.

Or, alternatively please contact Professor Roberts on Tel: 02078822161 NECLES COPD Clinical Lead

If you have concerns about the way you have been treated by health care professionals or the healthcare system whilst treated for your COPD you should contact the Patient Advice and Liaison Service (PALS) for further advice and information on how to make a complaint can be found on the following website www.pals.nhs.uk or alternatively contact Matthew Hodson on 0208 510 5107. Or Matthew's academic supervisor Dr. Sally Kiburn on 023 9284 2847

12 What are the side effects of any treatment received when taking part?

There are no additional risks.

13 What are the possible benefits of taking part?

There are no direct benefits to taking part in this study what we hope to be able to achieve is that we can understand about the experience of people living with COPD that could help shape future service provision for future people with COPD in local communities.

14 What happens when the research study stops?

You will only be asked to complete the questionnaires twice.

15 What if there is a problem and Contact Details for further information:

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

For Complaints or Further Information please contact:

Matthew Hodson
Nurse Consultant, Homerton Hospital - Tel: 020 8510 5107
Or email: matthew.hodson@homerton.nhs.uk

16 Who is organising and funding the research?

The principle researcher is Matthew Hodson, who is undertaking the project as part of his work with the British Lung Foundation, and Doctorate Studies at University of Portsmouth.

The funding for this project : UCL Partners in collaboration with Royal College of Physicians.

Below are the contact details of the Clinical lead of the COPD work in NECLES if you wish to discuss the study with him. But if you do have any concerns please do not hesitate to discuss this Matthew Hodson.

Professor Mike Roberts
NECLES COPD Clinical Lead Tel: 0207882216 Email: c.m.roberts@qmul.ac.uk

APPENDIX SIX

CONSENT FORM

Title of project:

The development of a patient reported experience measure in
Chronic Obstructive Pulmonary Disease (COPD) Stage 2 (PREM-COPD)

Investigator: Matthew Hodson

Centre Number: Study Number: Patient Identification Number for this trial:

Please initial box to indicate agreement

1.	I confirm that I have read and understand the information sheet dated 19.1.13 (version 1.3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3.	I agree for demographic data (including gender, age, severity of lung disease, medications, hospital information on flare up's, smoking history and lung function results) to be used or collected by the research team from my hospital doctor and/or general practitioner.	
4.	I agree to complete the questionnaires in the COPD pack and return an additional COPD pack a week later in the self addressed envelope to the research team. A unique number has been given to me indicated above.	
5.	I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from Homerton University Hospital and from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
6.	I agree to take part in the above study.	

Name of Patient

Date

Signature

Name of Person taking consent
(if different from Investigator)

Date

Signature

Investigator (if witnessed)

Date

Signature

1 copy for Patient, 1 for Investigator

Version: 1.2 (19/1/2013)

Page 1 of 1

IRAS: 12/LO/2022

APPENDIX SEVEN

Your name:

Today's date:



How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy 0 1 **X** 2 3 4 5 I am very sad

			SCORE
I never cough	0 1 2 3 4 5	I cough all the time	
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	0 1 2 3 4 5	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 5	When I walk up a hill or one flight of stairs I am very breathless	
I am not limited doing any activities at home	0 1 2 3 4 5	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	I am not at all confident leaving my home because of my lung condition	
I sleep soundly	0 1 2 3 4 5	I don't sleep soundly because of my lung condition	
I have lots of energy	0 1 2 3 4 5	I have no energy at all	
			TOTAL SCORE

Global Rate of Change

Study No:

My general health compared to last week is:

No	Global Rate of Change:
1	Much better
2	Somewhat better
3	About he same
4	Somewhat worse
5	Much Worse

Hospital Anxiety and Depression Scale (HADS)

Study Number:

Date:

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings, he or she will be able to help you more.

This questionnaire is designed to help your clinician to know how you feel. Read each item below and **underline the reply** which comes closest to how you have been feeling in the past week. Ignore the numbers printed at the edge of the questionnaire.

Don't take too long over your replies. Your immediate reaction to each item will probably be more accurate than a long, thought-out response.

A	D			A	D
3		1. I feel tense or 'wound up'	8. I feel as if I am slowed down		3
2		○ Most of the time	○ Nearly all the time		2
1		○ A lot of the time	○ Very often		1
0		○ From time to time, occasionally	○ Sometimes		0
		○ Not at all	○ Not at all		
	0	2. I still enjoy the things I used to enjoy	9. I get a sort of frightened feeling		0
	1	○ Definitely as much	like "butterflies" in the stomach		1
	2	○ Not quite so much	○ Not at all		2
	3	○ Only a little	○ Occasionally		3
		○ Hardly at all	○ Quite often		
			○ Very often		
3		3. I get a sort of frightened feeling as if	10. I have lost interest in my appearance		3
2		something awful is about to happen	○ Definitely		2
1		○ Very definitely and quite badly	○ I don't take as much care as I should		1
0		○ Yes, but not too badly	○ I may not take quite as much care		0
		○ A little, but it doesn't worry me	○ I take just as much care as ever		
		○ Not at all			
	0	4. I can laugh and see the funny side of	11. I feel restless as if I have to be on the move		3
	1	things	○ Very much indeed		2
	2	○ As much as I always could	○ Quite a lot		1
	3	○ Not quite so much now	○ Not very much		0
		○ Definitely not so much now	○ Not at all		
		○ Not at all			
3		5. Worrying thoughts go through my head	12. I look forward with enjoyment to things		0
2		○ A great deal of the time	○ As much as I ever did		1
1		○ A lot of the time	○ Rather less than I used to		2
0		○ Not too often	○ Definitely less than I used to		3
		○ Very little	○ Hardly at all		
	3	6. I feel cheerful	13. I get sudden feelings of panic		3
	2	○ Never	○ Very often indeed		2
	1	○ Not often	○ Quite often		1
	0	○ Sometimes	○ Not very often		0
		○ Most of the time	○ Not at all		
0		7. I can sit at ease feel relaxed	14. I can enjoy a good book or radio or		0
1		○ Definitely	TV programme		1
2		○ Usually	○ Often		2
3		○ Not often	○ Sometimes		3
		○ Not at all	○ Not often		
			○ Very seldom		

MRC DYSPNOEA SCALE

Study No:

Grade	Degree of breathlessness related to activities:
1	Not troubled by breathlessness except on strenuous exercise
2	Short of breath when hurrying or walking up a slight hill
3	Walks slower than contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own pace
4	Stops for breath after walking about 100 m or after a few minutes on level ground
5	Too breathless to leave the house, or breathless when dressing or undressing

APPENDIX EIGHT

NRES Committee London - Bloomsbury

HRA NRES Centre Manchester
Barlow House 3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7815
Facsimile: 0161 625 7299

29 January 2013

Mr Matthew Hodson
Nurse Consultant - COPD
Homerton University Hospital
Homerton Row
Hackney
London
E9 6SR

Dear Mr Hodson

Study title:	Developing a Patient Reported Experience Measure for Chronic Obstructive Pulmonary Disease (PREM-COPD) - Stage II
REC reference:	12/LO/2022
IRAS project ID:	116806

Thank you for your letter of 24 January 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Dr Ashley Totenhofer, nrescommittee.london-bloomsbury@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering Letter		03 December 2012
REC application	3.4	04 December 2012
Protocol	Version 1.2	03 December 2012
Evidence of insurance or indemnity	Zurich Municipal	20 July 2012
Questionnaire: PREM-COPD	Version 1.3	03 December 2012
Advertisement	Version 1.0	
Other: NECLES HIEC - PREM-COPD Final Report		22 February 2012
Investigator CV	Sally Kilburn	
Investigator CV	Janelle Yorke	
Questionnaire: COPD Assessment Test	Validated	
Questionnaire: Hospital Anxiety and Depression Scale (HADS)	Validated	
Questionnaire: Global Rate of Change Questionnaire	Validated	
Questionnaire: MRC Dyspnoea Scale	Validated	
Covering Letter		22 January 2012
Investigator CV	Matthew Hodson - 2013	

Participant Information Sheet	1.3	19 January 2013
Participant Consent Form	1.2	19 January 2013
Response to Request for Further Information		24 January 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

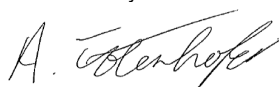
Further information is available at National Research Ethics Service website > After Review

12/LO/2022	Please quote this number on all correspondence
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We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely



Signed on behalf of:
Reverend James Linthicum
Chair

Email: nrescommittee.london-bloomsbury@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Mrs Linda Legrand - Homerton University Hospital

Dr Sally Kilburn – University of Portsmouth

Dr Janelle Yorke – University of Manchester

Professor Mike Roberts – Barts and the London School of Medicine and Dentistry

Denise Teasdale – Portsmouth University

APPENDIX NINE

FORM UPR16

Research Ethics Review Checklist



Please complete and return the form to Research Section, Quality Management Division, Academic Registry, University House, with your thesis, prior to examination

Postgraduate Research Student (PGRS) Information		Student ID:	eco51458
Candidate Name: Matthew Hodson			
Department:	School of Health Sciences & Social Work	First Supervisor:	Dr. Sally Kilburn
Start Date: (or progression date for Prof Doc students)		September 2012	

Study Mode and Route:	Part-time	<input type="checkbox"/>	MPhil	<input type="checkbox"/>	Integrated Doctorate (NewRoute)	<input type="checkbox"/>
	Full-time	✓	MD	<input type="checkbox"/>	Prof Doc (PD)	✓
			PhD	<input type="checkbox"/>		

Title of Thesis:	The development of a patient reported experience measure in chronic obstructive pulmonary disease (COPD)
Thesis Word Count: (excluding ancillary data)	

If you are unsure about any of the following, please contact the local representative on your Faculty Ethics Committee for advice. Please note that it is your responsibility to follow the University's Ethics Policy and any relevant University, academic or professional guidelines in the conduct of your study


Although the Ethics Committee may have given your study a favourable opinion, the final responsibility for the ethical conduct of this work lies with the researcher(s).

UKRIO Finished Research Checklist:

(If you would like to know more about the checklist, please see your Faculty or Departmental Ethics Committee rep or see the online version of the full checklist at: <http://www.ukrio.org/what-we-do/code-of-practice-for-research/>)

a) Have all of your research and findings been reported accurately, honestly and within a reasonable time frame?	YES
b) Have all contributions to knowledge been acknowledged?	YES
c) Have you complied with all agreements relating to intellectual property, publication and authorship?	YES
d) Has your research data been retained in a secure and accessible form and will it remain so for the required duration?	YES
e) Does your research comply with all legal, ethical, and contractual requirements?	YES

*Delete as appropriate

Candidate Statement:	
I have considered the ethical dimensions of the above named research project, and have successfully obtained the necessary ethical approval(s)	
Ethical review number(s) from Faculty Ethics Committee (or from NRES/SCREC):	NRES Committee London – Bloomsbury REC: 12/LO/2022
Signed: <i>(Student)</i>	Date: 26/09/2014
	
If you have <i>not</i> submitted your work for ethical review, and/or you have answered 'No' to one or more of questions a) to e), please explain why this is so:	
Signed: <i>(Student)</i>	Date:

Homerton University Hospital

NHS Foundation Trust

Research & Development Committee
Chair: Dr Narendra Aladangady

Linda Legrand
Research & Development Manager
Linda.legrand@homerton.nhs.uk

Homerton University Hospital
Research and Development
Yellow Roof Top Office
Homerton Row
London
E9 6SR

Tel: 020 8510 5134
Fax: 020 8510 7850
www.homerton.nhs.uk

Mr Matthew Hodson
COPD Nurse Consultant
Department of Respiratory Medicine
Homerton University Hospital NHS Foundation Trust
Homerton Row
London E9 6SR

8th February 2012

Dear Mr Hodson

Re: Research Study "Developing a Patient Reported Experience Measure for Chronic Obstructive Pulmonary Disease (PREM-COPD) - Stage II"
Homerton R&D: No RE1302 REC Reference: 12/LO/2022

Thank you for sending all the relevant documents for Homerton University Hospital Trust Research and Development Approval of the above research study. As part of the Research and Development approval process we have conducted a site specific assessment for this study. I am happy to inform you that the Trust will sponsor this study and has approved the conduct of the study and that the Trust will indemnify against negligent harm that might occur during the course of this project.

The following main document/s has been received by R&D department as part of the approval process;

Protocol Version 1.2. Dated 3rd February 2012
Patient/participants information sheet Version 1.3. Dated 19th January 2013
Consent form Version 1.2. Dated 19th January 2013

All other document/s you have sent in as part of this process has also been received.

I would like to draw your attention to the following conditions of the approval of this research project with which you must comply: **Failure to do so may result in the Trust withdrawing R&D approval allowing you to conduct this research project at Homerton University Hospital NHS Foundation Trust.**

Untoward events - Should any untoward event occur it is **essential** that you complete a clinical incident form and write on the form 'R&D'. Contact the R&D Office immediately and if patients or staff are involved in an incident you must also contact the Risk Manager on 020 8510 7649.

Status of Research - Inform us if your project is amended or if your project terminates early/requires an extension as well as informing the Research Ethics Committee. This is necessary to ensure that your indemnity cover is valid and also helps the office to maintain up-to-date records. A copy of any publications arising from the research should be sent to the R&D Office for use in the R&D Annual Report. Please be reminded that this hospital should be acknowledged in any publication.

Incorporating hospital and community health services, teaching and research

Research Information - You will be required to complete a project update form as required by the R&D Office to ensure that we have up to date information to enable us to send accurate reports to the DoH and the research networks. The project update form will be emailed or sent to you by the R&D Office.

Research Governance - As part of research governance, all investigators accessing identifiable personal information are required to comply with current data protection requirements..

Intellectual Property - If you believe that protectable intellectual property may rise from your research, please contact the Linda Legrand R&D Manager on ext 5134 who will advise you on the proper course of action.

Monitoring of Studies - You must comply with the Trust's legal responsibility as sponsor to monitor and audit research studies to ensure that the Research Governance Framework and Good Clinical Practice (GCP) if applicable is being adhered too. Monitoring questionnaires will be sent to you at least once a year. Random audit visits will also take place across the trust and will be conducted following at least a seven day notice period. **Failure to respond to any of these monitoring or auditing requests may result in the Trust withdrawing as sponsor to this research project and consequently the research project will have to be suspended until the Chief Investigator can identify and confirm a new sponsor for the study.**

Please note that all NHS and social care research is subject to the DoH *Research Governance Framework*. If you are unfamiliar with the standards contained in this document, you may obtain details from the Trust R&D Office or from the DoH website (www.dh.gov.uk).

Please do not hesitate to contact me or Linda Legrand, Research and Development Manager if you have any further questions.

Yours sincerely,



Dr Narendra Aladangady
Director Research & Development



Dear Matt,

Thank you for contacting us about your study into patient reported experience measures in COPD.

You are welcome to invite our Breathe Easy members to take part in your study. I would also be happy to send out a communication on your behalf to let them know about it and tell them how to get in touch with you.

The research protocol looks good and the patient information sheet is very clear. I think our group members will find it easy to understand.

Please let me know if we can provide any further assistance.

Kind regards,

A handwritten signature in black ink, appearing to be 'BB', is located below the 'Kind regards,' text.

Bethany Bateman
Stakeholder Engagement Manager

T: 020 7688 5557
M: 07792 767 356
E: bethany.bateman@blf.org.uk

University Hospital of South Manchester

NHS Foundation Trust

Research & Development Directorate
Ground Floor, Education & Research Centre
Tel: 0161 291 5777 Fax: 0161 291 5771
Faye.O'Keefe@manchester.ac.uk

Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
M23 9LT
Tel: 0161 998 7070

Ms Marion Wood
Clinical Specialist Physiotherapist and COPD Service Lead
University Hospital of South Manchester NHS Foundation Trust
Wythenshawe Hospital
Southmoor Road
Manchester
M23 9LR

5 July 2013

Dear Ms Wood

Study Title: Developing a Patient Reported Experience Measure for Chronic Obstructive Pulmonary Disease (PREM-COPD) – Stage II
R&D Ref: 2013RM010
REC Ref: 12/LO/2022

Thank you for providing all of the documentation for the above study.

I am pleased to inform you that the above referenced study has been given Trust R&D approval and you may begin your study at University Hospital of South Manchester NHS Foundation Trust.

The approval has been granted for the duration of the REC approval for the study.

The list of documents reviewed and approved for use are as follows:

Document	Version	Date
Covering Letter		3 December 2012
Protocol	1.2	3 December 2012
Evidence of insurance or indemnity	Zurich Municipal	20 July 2012
Questionnaire: PREM-COPD	1.3	3 December 2012
Investigator CV	Janelle Yorke	
Questionnaire: COPD Assessment Test	Validated	
Questionnaire: Hospital Anxiety and Depression Scale (HADS)	Validated	
Questionnaire: Global Rate of Change Questionnaire	Validated	
Questionnaire: MRC Dyspnoea	Validated	
Participated Information Sheet	1.3	19 January 2013
Participant Consent Form	1.2	19 January 2013
R&D Form	116806/410360/14/91	



Chairman - Felicity Goodey, CBE, DL
Chief Executive - Julian Hartley, BA, MBA



For your information I confirm we have the corresponding regulatory approval letters for each of the current approved documents listed above.

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, Good Clinical Practice, Trust policies and procedures, and all applicable legislation including, but not limited to, the Data Protection Act, the Health and Safety at Work Act, Human Tissue Act, Medicines for Human Use (Clinical Trials) Act. As Principal Investigator you retain overall responsibility for compliance with these requirements by all members of the research team.

The recruitment target is 40 participants for this study. This study is subject to external performance management of recruitment on time and to target. You are responsible for ensuring that recruitment targets are met. **The Trust expects the first participant to be recruited within 30 days of receipt of R&D approval.** The R&D department must be informed of the date on which the first participant is recruited. You may delegate this responsibility to the CTU or a responsible member of your research team. If there is a delay in starting recruitment, you must inform the R&D office and give a reason for this. You are also required to provide recruitment data to the R&D office upon request. This information will be used to inform performance targets, which will be reported to the Trust Board.

You are required to affix the enclosed labels on the BACK INSIDE COVER of each participant's casenotes. You will need to define the '*do not destroy before*' date according to the minimum term defined in the REC application. You are also required to document the patient's participation on the alert page at the front of the participant's casenotes. These requirements are Trust Policy and are necessary to ensure that the Trust retains the case notes for the period of time required for research records.

All researchers involved in the study must have undertaken GCP training within the last two years. Please ensure that you provide the R&D office with evidence of this.

You must obtain R&D approval (or acknowledgement) for all amendments during the course of the study. Substantial amendments must not be implemented until R&D approval has been granted. You should submit all amendment documentation to the R&D office for review.

You must ensure that annual reports are submitted to the REC in a timely fashion, and a copy should also be sent to R&D. On completion of the study you must ensure that the End of Study Report is submitted to the REC, and a copy sent to R&D. More information on post-approval requirements is available from <http://www.nres.nhs.uk/applications/after-ethical-review/>

You must inform the R&D office of any changes to the management of your project, any extensions to the study, and any changes in funding, if applicable.

The Trust may monitor the progress or audit the conduct of your study at any time. The Trust reserves the right to suspend or withdraw R&D approval if you do not adhere to the requirements outlined. You must abide by all determinations of the R&D office and accept their final authority.

The R&D office must be notified of any Serious Adverse Events (SAEs) which are probably or definitely related to the trial, and any Suspected Unexpected Serious Adverse Reactions (SUSARs), promptly.

Should you have any queries, or feel that we can be of assistance, please do not hesitate to contact a member of the R&D office at uhsm.rd@manchester.ac.uk or on 0161 291 5768.

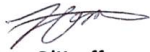


Chairman - Felicity Goodey, CBE, DL
Chief Executive - Julian Hartley, BA, MBA



I would like to take this opportunity to wish you well with your research.

Yours sincerely



Faye O'Keeffe
Research Governance Co-ordinator
University Hospital of South Manchester NHS Foundation Trust

cc *Dr Janelle Yorke, Senior Lecturer, University of Manchester*



Chairman - Felicity Goodey, CBE, DL
Chief Executive - Julian Hartley, BA, MBA





Barts and The London
School of Medicine and Dentistry

Professor C.M. Roberts
Dean for Students
Garrod Building
Turner Street, London, E1 2AD
Tel: +44 (0) 20 7882 2126 (P.A.)
Fax: +44 (0) 20 7882 5684
j.conner@qmul.ac.uk (P.A.)

February 20, 2013

To Whom it May Concern

Re: **PREM – COPD Stage 2**
Matthew Hodson,

I have peer reviewed the above protocol and agree with the methodology and analysis of the proposal and that this is a study worthy of further research.

Yours sincerely

Professor Mike Roberts
Dean for Students

APPENDIX TEN

The development of a patient reported experience measure in COPD – using the Rasch Model

Matthew Hodson¹

Dr Janelle Yorke²

Professor C Michael Roberts³

Professor Sharon Andrew⁴

Professor Paul Jones⁵

1. ACERS Team, Homerton University Hospital, London UK

2. School of Nursing, Midwifery and Social Work, Manchester University, Manchester UK

3. Barts and The London School of Medicine and Dentistry, Queen Mary University of London

4. Faculty of Health, Social Care & Education, Anglia Ruskin University, Essex UK

5. Institute for Infection and Immunity, St George's University of London, London UK

Homerton University Hospital **NHS**
NHS Foundation Trust



Introduction:

Experience of patients with chronic obstructive pulmonary disease (COPD) and their views on the quality of their healthcare is not currently captured in patient reported measures.

Aim:

To develop and validate a patient reported experience measure (PREM) to assess experiences of living with chronic obstructive pulmonary disease and perceived quality of healthcare provision.

Method:

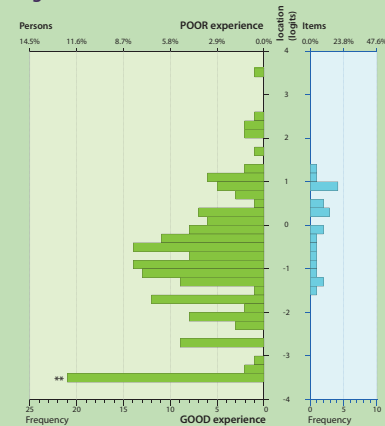
Previous work with 83 COPD patients identified 38 items for potential PREM inclusion. These, together with the COPD Assessment Test (CAT) and Hospital Anxiety & Depression Scale (HADS) were administered to patients with COPD. Items demonstrating significant gender/age bias ($p < 0.05$), floor or ceiling effects (at 40%), missing data $> 15\%$, or high item-item correlations ($r > 0.8$) were removed. Rasch analysis was applied to the remaining items.

Results:

174 patients (Mean age 71, SD 9; 91 female; Mean FEV1% predicted 59, SD 21.9) were studied. 29 items were removed providing a 9-item unidimensional scale ($\chi^2 p = 0.71$) with a wide scaling range (logits from -0.1 to +0.2, Figure 2).

These cover experiences of living with COPD (I feel that I am in control of my condition) and health care (I am concerned that my GP will not listen to my point of view). Internal consistency was good ($\text{Psi} = 0.75$) and correlations between the PREM-COPD, CAT & HADS were moderate ($r = 0.42$, $r = 0.30$ respectively).

Figure 1 Person-item threshold distribution



**The spike at the lower end (good experience) suggests that there was a high proportion of participants who had a better experience than others, scoring a 0 score on the 9 items overall.

Figure 2 Individual Item Fit for 9 Items

Item	Item	Mean	SD	Logits	Item	Mean	SD	Logits	Item	Mean	SD	Logits
1	13	34	10	1.13	1	13	34	10	1.13	1	13	34
2	4	14	10	1.13	2	4	14	10	1.13	2	4	14
3	11	28	10	1.13	3	11	28	10	1.13	3	11	28
4	12	32	10	1.13	4	12	32	10	1.13	4	12	32
5	10	26	10	1.13	5	10	26	10	1.13	5	10	26
6	7	22	10	1.13	6	7	22	10	1.13	6	7	22
7	8	21	10	1.13	7	8	21	10	1.13	7	8	21
8	15	38	10	1.13	8	15	38	10	1.13	8	15	38
9	16	39	10	1.13	9	16	39	10	1.13	9	16	39

Figure 3 Spearman's rho correlation between total scores of the COPD PREM-9 and COPD Assessment Test (CAT) in 174 patients.

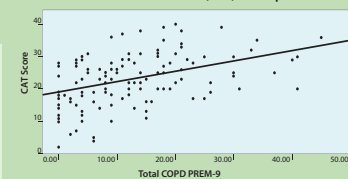


Figure 3 shows there is a weak association ($r = 0.42$) demonstrating the PREM is measuring something different from impaired health status.

Figure 4 Three identified themes with examples taken from the COPD PREM-9 Questionnaire

USUAL CARE IN COPD -
These questions relate to the everyday usual care given for your COPD

3 I understand how my COPD treatments work 1 2 3 4 5 I am confused about how my COPD treatments work

MY EVERYDAY LIFE WITH COPD
These questions relate to your everyday life with COPD

6 I feel that I am in control of my condition 1 2 3 4 5 I feel that I do not have any control over my condition

COPD EXACERBATION (Flare up)
These questions relate to a flare up of your COPD

8 I am confident that in a 'flare up' I have quick access to treatment like a rescue pack or access to my GP/nurse 1 2 3 4 5 I am worried that in a 'flare up' I do not have quick access to treatment like a rescue pack or access to my GP/nurse

Conclusion

The COPD-PREM demonstrated good internal reliability and showed a wide scaling range suggesting regardless of severity people with COPD can have good or bad experiences. There were low to moderate correlations with the CAT & HADS suggesting the PREM-COPD measures a different concept to health status. The COPD-PREM should provide a useful measure of patients' experience with care that complements measures of health status and mood.

Copies of report could be obtained from Matthew Hodson: matthew.hodson@homerton.nhs.uk

APPENDIX ELEVEN

CASP Screening Questions - Systematic Review
(Adapted from CASP Critical Appraisal Skills Programme www.casp.net)

Study: Giacomini, M., DeJean, D., Simeonov, D., & Smith, A. (2012). Experiences of living and dying with COPD: a systematic review and synthesis of the qualitative empirical literature. *Ontario Health Technology Assessment Series*, 12(13), 1–47

Section A: Are the results of the review valid?

1. Did the review address a clearly focused question? X Yes ☐ Can't tell ☐ No

There was a clear research focused question focusing on the patient, carer and healthcare professional. The COPD population was being studied - but it wasn't that clear on the severity of population being studied. There were clear inclusion and exclusion criteria set.

The intervention was clear in terms of the papers needed to focus on experience in any aspect of COPD for example studies addressing topics other than the experiences of living or dying with COPD from the perspective of persons at risk, patients, health care providers, or informal carers were excluded from the study.

The outcomes from the studies were clearly identified and summarised making a thematic account of pooled information.

2. Did the authors look for the right type of papers? X Yes ☐ Can't tell ☐ No

The main objective of the analysis was to review empirical qualitative research on the experiences of patients with chronic obstructive pulmonary disease (COPD), informal caregivers ("carers"), and health care providers—from the point of diagnosis, through daily living and exacerbation episodes, to the end of life. A wide variety of articles which addressed this objective were included in the systematic search with a clear PRISMA tree evident on the decisions to include or not include articles.

The study designs were qualitative in nature with aims to explore or understand the experiences of living with COPD, and from the results of the systematic review useful themes were evident.

Section B: What are the results?

3. Do you think all the important, relevant studies were included? X Yes ☐ Can't tell ☐ No

A 10 year history was covered, Literature searches for studies published from January 1, 2000 to November 2010 were identified using OVID MEDLINE; ISI Web of Science; and Cumulative Index to Nursing and Allied Health Literature (CINAHL). It was identified that the Titles and abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained.

It was identified that a further 1 study was identified whilst undertaking the review, however there is no mention of any additional studies being reviewed through the 'grey literature' or a search for unpublished work and the systematic review also excluded non-English language studies, so there is a potential that some studies with relevance could have been missed and not included overall.

4. Did the review's authors do enough to assess X Yes ☐ Can't tell ☐ No the quality of the included studies?

Full papers were retrieved and read by two investigators. Papers were grouped by broad topical focus and read closely by one investigator to generate a narrative summarizing the main findings under each topic. A second investigator reviewed the same papers, revised the narrative (by consensus with the first reviewer), and incorporated any relevant findings from papers in other topic groups (for example, some papers on smoking experiences also addressed day-to-day living issues). In all, each primary research paper was reviewed two to three times by at least two investigators.

A synthesis was developed to relate the findings to the clinical trajectory of COPD, highlighting key patient, caregiver, and health care provider experiences reported at specific phases of the disease course. Drafts of the full report were presented sequentially to the Ontario Health Technology Advisory Committee, the Medical Advisory Secretariat, and the COPD Expert Panel for multidisciplinary feedback.

A weakness of this systematic review is that it does not clearly identify areas of weakness of the papers identified. It was clear they were identified because of clinical relevance but the paper does not highlight many aspects about the papers themselves.

5. If the results of the review have been combined, X Yes Can't tell ☐ No was it reasonable to do so?

This paper makes a reference to a second investigator reviewing the same papers, and a revised narrative (by consensus with the first reviewer) completed for publication. This process I feel adds value to ensure that the themes which have been combined are appropriate and relevant to the research question. The review incorporates any relevant findings from papers in other topic areas which primarily are not concerned with the patient experience of living with COPD an example includes some of the papers reviewed were specifically on people's experience of smoking, but also addressed the day-to-day living with COPD, thereby appropriately combining. To ensure accuracy and improve quality each primary research paper was reviewed two to three times by the two investigators.

6. What are the overall results of the review?

The findings of the systematic review covered 4 broad categories of patient experiences over the course of COPD: diagnosis, living day-to-day, exacerbations, and the end of life. A fifth category addressed carer experiences - these categories were not dissimilar to the findings of Study One addressed within this thesis of our own work.

As this review only explores qualitative results, no numerical data featured in the systematic review

7. How precise are the results?

It was difficult to quantify how precise the results were but the 5 themes identified were of high relevance and from a clinical perspective were appropriate and can be used within the clinical setting. The results were highly informative and gave the reader a comprehensive overview of the experiences of people living with COPD.

A criticism however is the relevance of the papers to the classification of the disease or the number of years people had been living with COPD - therefore these results have been pooled together with little explanation and remain unclear from the literature how long someone had been living with the disease or the severity of their disease, along with other demographics such as age or gender.

Section C: Will the results help locally?

8. Can the results be applied to the local population? X Yes ☐ Can't tell ☐ No

From my experience and reading of patient experience, this systematic review highlights some very interesting and key points into the experience of COPD. The themes identified give a clear message about 5 themes identified within the systematic review. These results can be applied to a local population.

9. Were all important outcomes considered? X Yes ☐ Can't tell ☐ No

This systematic review has clearly answered the initial research question 'What do patients with COPD, their informal caregivers ("carers"), and health care providers experience over the course of COPD? The review clearly identified a significant number of papers within the literature on patient experience of COPD, identifying over 100 articles for inclusion. The authors identified the five themes which are relevant to current outcomes and topical subjects in COPD. It addresses and quotes some powerful examples of these experiences of patients, which has now become saturated within the literature.

This systematic review clearly identifies the need for improvement and the need for measurement as not much has changed over the 10 year period studied.

10. Are the benefits worth the harms and costs? X Yes ☐ Can't tell ☐ No

This is an informative study that clearly identifies the harm that an incorrect diagnosis and the effects being diagnosed with COPD has on patients' lives. The mostly negative experience is well documented and the results this has on people living with COPD throughout their lives is clearly evident, many resulting in high anxiety and depression with a high need for healthcare services.

CASP Screening Questions - Systematic Review
(Adapted from CASP Critical Appraisal Skills Programme www.casp.net)

Study: Disler, R. T., Green, A., Luckett, T., Newton, P. J., Currow, D., & Davidson, P. M. (2014). Experience of Advanced Chronic Obstructive Pulmonary Disease: Metasynthesis of Qualitative Research. *Journal of Pain and Symptom Management*.

Section A: Are the results of the review valid?

1. Did the review address a clearly focused question? ☐ Yes ☒ Can't tell ☐ No

A research question was not addressed specifically but a clear objective was stated which was to 'to increase understanding of the experience and ongoing needs of individuals living with COPD', however, the articles makes several references that the reason for metasynthesis is to answer 'complex research questions'.

The population was not specially identified in the article except that the title and further reading makes reference to 'advanced COPD' but the objective does not support this suggesting that that it was looking at individuals with COPD', there are no reference to spirometry results of the articles chosen. There is a clear focus on how the metasynthesis was undertaken and the outcome of the study was clearly reviewed and understood.

A further aim is also introduced as to 'increase the understanding of the experience and ongoing needs of individuals living with COPD and has unique potential for informing the coordination and responsiveness of services to the needs of individuals with COPD and their families'.

2. Did the authors look for the right type of papers? ☒ Yes ☐ Can't tell ☐ No

In total, twenty-two studies were included in the review. This was a variety of studies looking at the qualitative aspects of living with COPD. The appropriateness of study design or subjects however, was not commented on by the author of the articles that were included within the metasynthesis. But having reviewed the titles of the journals included, many were appropriate, however the severity of the COPD was difficult to gage as not all articles had 'severe' or 'advanced' in the title. But Disler does make a clear comment in the introduction that 'the clear benefit of this individual perspective, small sample sizes and inherent absence of generalisation limit the capacity to incorporate this information in policy, practice and research'.

Section B: What are the results?

3. Do you think all the important, relevant ☐ Yes ☐ Can't tell ☐ No studies were included?

Medline, PsychINFO, CINAHL, and Sociological Abstracts were searched for articles published between January 1990 and December 2012. Metasynthesis of qualitative data followed the principles of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). This is a reasonable data search and the appropriate databases were searched. However, there was no mention of searching the 'grey' literature or other

forms of data collection, this potentially could have disadvantaged the review due to a number of known unpublished formal work not being included.

The analysis focussed on twenty-two studies. Four hundred and twenty-two free codes were condensed into seven descriptive themes: better understanding of condition; breathlessness; fatigue; frailty; anxiety; social isolation; and loss of hope and maintaining meaning. These seven themes were condensed further into three analytical themes that described the experience and ongoing needs of individuals with COPD: the need for better understanding of condition; sustained symptom burden; and the unrelenting psychological impact of living with COPD.

4. Did the review's authors do enough to assess X Yes ☐ Can't tell No the quality of the included studies?

The study was also undertaken with the supervision of a health informatics expert which adds value to the fact that only published work was reviewed.

There was a good section examining the quality of the studies examined and clearly highlight that 'the majority of studies presented had clear aims, outlined the qualitative approach used and described data collection techniques. Studies did not consistently justify the qualitative research design. Sampling techniques were assessed as having limited capacity to support generalizability to other contexts' And makes suggestions that this is to be expected in small cohort qualitative research and was discussed as a limitation in most studies, however there were a number of different methods of data collection within the studies used such as interview, focus groups and open-ended questions.

More importantly Disler et al. (2014) also evaluated for 'adherence, clarity of aims, justification of approach, procedural rigor, representativeness of the sample, interpretation of the data, reflexivity and evaluative rigor, and transferability of findings', key areas to ensure appropriate quality within a metasynthesis.

5. If the results of the review have been combined, X Yes ☐ Can't tell ☐ No was it reasonable to do so?

The results within this metasynthesis have been combined and descriptive and analytical themes were developed through thematic synthesis and expert panel discussion of extracted primary quotes and not the primary data itself. This is helpful to get a good understanding of how the impact of the disease affects individuals living with COPD. The article gives a clear focus to the reason articles were chosen.

6. What are the overall results of the review?

An initial thematic synthesis of qualitative data was completed in three stages using electronic software (EPPI-Reviewer 4) for qualitative coding, also for quality purposes, independent investigators were also used. This process appears clear and the quality of this is well documented using appropriate software to support the handling of the data extracted and to make sense of the data through discussion and experts.

The article has used an appropriate literature search and then followed the principles of the Preferred Reporting Items for Systematic Reviews and Meta- Analyses (PRISMA), which is commonly used method in this type of study. The overall results of the study

highlight 3 main themes of living with COPD which are of high relevance and the script can be translated across the advanced COPD population.

7. How precise are the results?

It is difficult to quantify how precise the results were but the 3 themes identified were of high relevance and from a clinical perspective were appropriate and can be used further within the clinical setting. The results were highly informative and gave the reader a broad sense of the experience of living with COPD, generalised in this review format.

A criticism, however, is the relevance of the papers to the classification of the disease or the number of years people had been living with COPD - therefore these results have been pooled together with little explanation and therefore remain unclear from the literature how long someone had been living with the disease or the severity of their disease, along with other demographics such as age or gender.

Section C: Will the results help locally?

8. Can the results be applied to the local population? ☒ Yes ☐ Can't tell ☐ No

I believe that this study has through an appropriate research approach captured some key points which can be applied to the local population for clinicians, researchers and the general population and been able to apply these results to a local population to use as guidance to explore further the themes locally to improve or understand 'generally' the concerns of patients living with COPD.

9. Were all important outcomes considered? ☒ Yes ☐ Can't tell ☐ No

It was acknowledged that despite a number of medications and advancements in COPD, individuals living with advanced COPD continue to experience symptom burden and have high rates of health care utilization.

Combining discrete qualitative studies has provided a useful perspective of the experience of living with COPD over the past two decades.

Disler., et al (2014) makes good recommendation that future research and resources should focus on solutions through the development of consumer-driven interventions that address patients' ongoing needs.

10. Are the benefits worth the harms and costs? ☐ Yes ☐ Can't tell ☐ No

This is an informative study that clearly identifies the harm that an incorrect diagnosis and the effects being diagnosed with COPD has on patients' lives. The mostly negative experience is well documented and the results this has on people living with COPD throughout their lives is clearly evident, many resulting in high anxiety and depression with a high need for healthcare services.

APPENDIX TWELVE

Ref: Guidance for Industry Patient-reported outcome measures: Use on medical product development to support labelling claims. US Department of Health and Drug Administration RDA December 2009

Conceptual Framework for the development of a Patient Reported Outcome (PRO) Instrument (FDA, 2009)

Concept	Iterative Process	Map against COPD PREM development
Identify Concepts and Develop Conceptual Framework	<ul style="list-style-type: none"> a) Identify concepts and domains that are important to patients. b) Determine intended population and research application. c) Perform literature review/expert review. d) Hypothesize expected relationships among concepts. e) Document preliminary instrument development. 	<ul style="list-style-type: none"> a) the intended population for the development of the PREM was very clear from the start in that it focused on COPD patients of all severities. The concepts measured were drafted from the themes identified within the cognitive interviewing of patients and also supported by the literature review on patient experience, supported by expert opinion. b) The initial concept of the PREM was undertaken in two studies – the initial study was undertaken as a project, however, Study Two had robust and rigorous research applications. c) Two detailed literature reviews were undertaken first to review the published literature on COPD PREMS (none) and secondly a review of the experiences of living with COPD and interaction with healthcare. d) a formal hypothesis written – but verbal ones were evident i.e. we knew COPD pts report poor experience and understood where these lay i.e. diagnosis and end of life care. e) the concept of the preliminary instrument development was mapped and an 'instrument' protocol was developed
Create Instrument	<ul style="list-style-type: none"> a) Generate items. b) Choose administration method recall period, and response scales. c) Draft instructions. d) Draft procedures for scoring and administration. e) Pilot test draft instrument. f) Refine instrument and procedures. 	<ul style="list-style-type: none"> a) Generation of items were undertaken in a robust and patient-centred manner using discovery interviews with the target population over 80 patients, and thematic analysis of themes including expert and patient involvement. 40 items generated. b) Paper instrument handed out and, if possible, completed at point of initial contact. Follow-up one week after with global rate of change and PREM questionnaire. Likert scale of 0-5 chosen by expert panel. c) Patient information sheet also written on the use of the instrument and how to complete. i.e. 0 = good experience; 5 = bad experience. d) Research protocol including data collection methods and instructions were completed and agreed by expert panel and ethics board. The administration was self-administration. e) Testing of draft instrument with a number of COPD patients prior to formal testing. f) Two items were deleted at this stage as they were not understood by patients in a cognitive interviewing process and therefore the instrument was refined. No changes to the patient information sheet were needed. Refinement of the 38-item instrument was undertaken with item-reduction and Rasch analysis.
	<ul style="list-style-type: none"> a) Assess score reliability, validity, and ability to detect 	<ul style="list-style-type: none"> a) Content validity was undertaken with the items which were generated and also mapped against current literature on patient experience. Construct

Assess Measurement Properties	<p>change.</p> <p>b) Evaluate administrative and respondent burden.</p> <p>c) Add, delete, or revise items.</p> <p>d) Identify meaningful differences in scores. Finalize instrument formats, scoring, procedures, and training materials.</p>	<p>validity was measured through item-reduction following an expert review. Remaining items were entered into the Rasch Model which mathematically analyses the total score - a series of tests were undertaken in a detailed process to test reliability and validity of remaining items. Though the instrument hasn't been examined to detect change, a test-re-test design was examined. Further validity study needs exploring post thesis in a different group of patients.</p> <p>b) It was acknowledged that asking 38 items plus the additional outcome measures were long and wanted to reduce the emotional or cognitive strain on patients. Therefore, advice on reducing the length of the questionnaire, formatting and font size was critical. These aspects needed further review on the final 9-items PREM.</p> <p>c) There were several stages in which the instrument was modified, starting from its initial construction of items through the process and expert panel and patients were involved in the decisions until a final 13 items were added into Rasch and then items were deleted due to the mathematical model and items not fitting a unidimensional model.</p> <p>d) As there was only one total score present in the construct of the questionnaire there was evidence in the Rasch analysis that there was a varying score of experience. Further work needs to be undertaken as set out in the FDA manual on the procedures and training materials for the instrument, including instructions on the use and advice/intervention on the final score. This will be completed as part of the expert group and further study.</p> <p>Criterion validity was difficult due to the fact that this is the first published instrument available and no 'gold standard' as stated by FDA (though it is acknowledged that normally there is no 'gold standard' available)</p>
Modify Instrument	<p>a) Change concepts measured:</p> <ul style="list-style-type: none"> - populations studied - research application - instrumentation - or method of administration 	<p>a) The instrument throughout its development has also measured the appropriate population (COPD), there has been a wide consultation of the severity of COPD and this was evident in the FEV1 highlighted. Further work, however needs to be undertaken exploring the instrument with groups of patients with varying levels of severity.</p> <p>Further work is also needed to understand the instrument and adapt or translate for different languages; more evidence on content validity and other measurement properties will be needed. Therefore the instrument is only available in English. The concept of the instrument remained focused throughout the development; it is a way of capturing data on patients' experience of living with COPD. The application and method of administration of the final COPD-PREM-9 is a short and focused instrument on experience of living with COPD; further work, however, will need to be undertaken on changing the instrument from paper to electronic, and understanding its use in areas such as clinics, pulmonary rehabilitation (PR) groups and a review of the order of the items.</p>